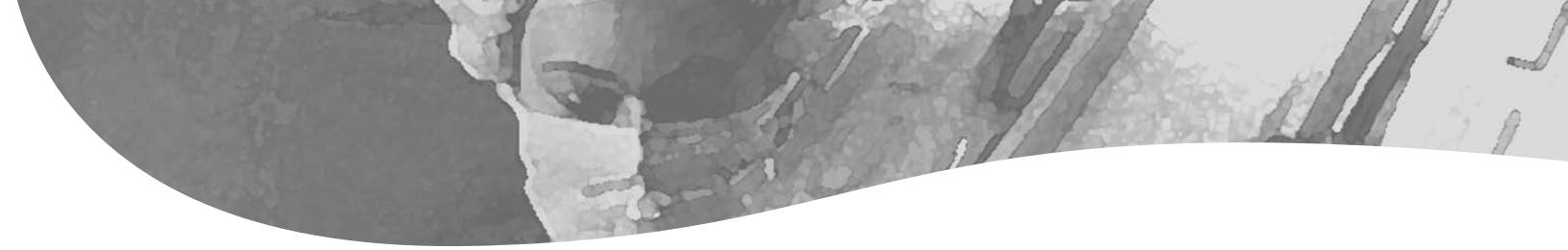

Valleylab™

User's Guide

ForceTriad™

Energy Platform

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the Valleylab ForceTriad™ energy platform only. Additional technical information is available in the ***ForceTriad™ Energy Platform Service Manual***.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

Equipment covered in this manual
ForceTriad™ energy platform

Valleylab Part Number 1004175
Effective Date September 2006

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Manufactured by
Valleylab
a division of Tyco Healthcare Group LP
Boulder, Colorado 80301-3299 USA

For information call
1-303-530-2300

European representative
Tyco Healthcare UK Ltd.
Gosport, PO13 0AS, UK

CE 0086

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Conventions Used in this Guide

Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

Caution

Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

Notice

Indicates a hazard which may result in product damage.

Important

Indicates *an operating tip or maintenance suggestion.*

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ForceTriad™ Energy Platform	One year from date of shipment
Electrosurgical Generators	One year from date of shipment
RFG-3C™ Plus Lesion Generator	One year from date of shipment
LigaSure™ Vessel Sealing System	One year from date of shipment
LigaSure™ Reusable Instruments	One year from date of shipment
Mounting Fixtures (all models)	One year from date of shipment
Footswitches (all models)	One year from date of shipment
Force Argon™ Units	One year from date of shipment
OptiMumm™ Smoke Evacuator	Two years from date of shipment
LigaSure™ Sterile Single Use Items	Sterility only as stated on packaging
Sterile Single Use Items	Sterility only as stated on packaging
Patient Return Electrodes	Shelf life only as stated on packaging

This warranty is in lieu of all other warranties, express or implied, including without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of Valleylab. Valleylab neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Valleylab's products.

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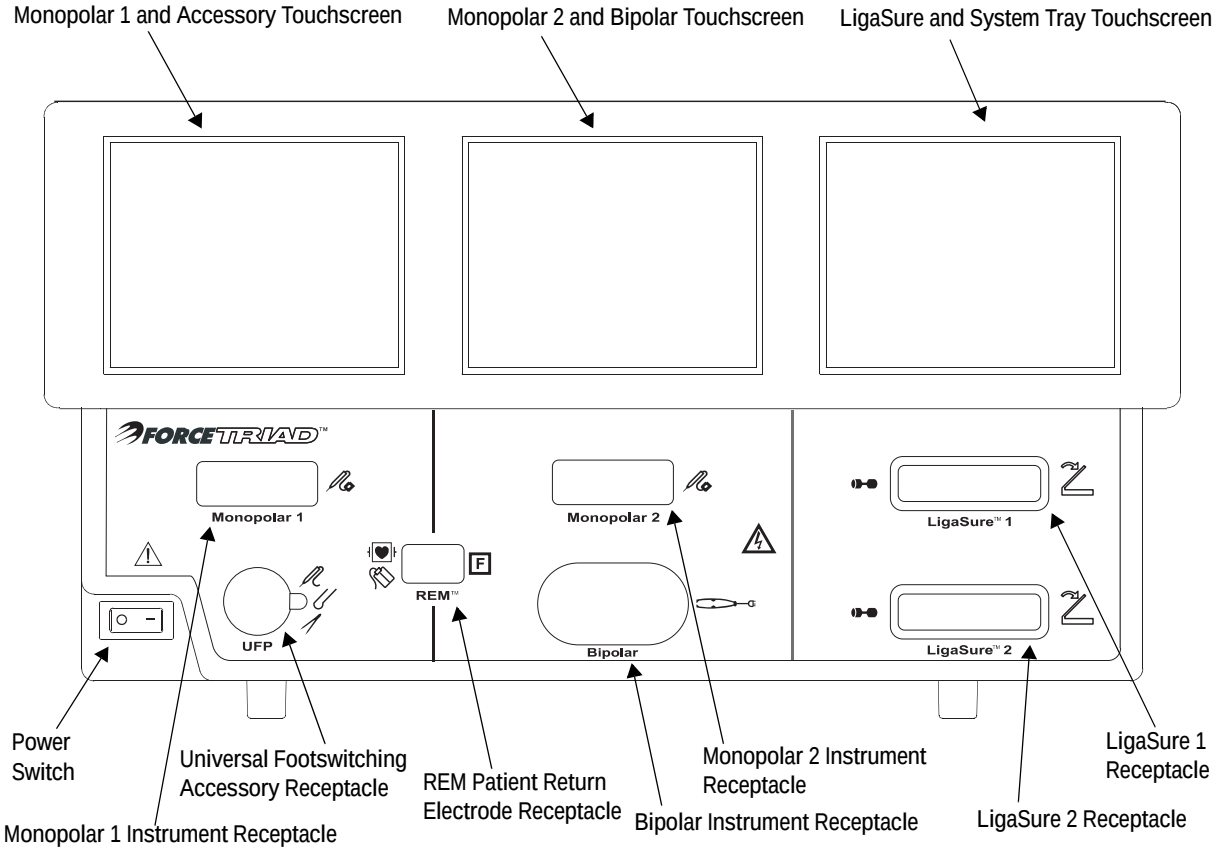
Chapter 1

ForceTriad Energy Platform Overview and General Features

This chapter provides an overview of the features and functions of the ForceTriad energy platform.

Caution
Read all warnings, cautions, and instructions provided with this system before use.
Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions for electrosurgical instruments are not included in this manual.

ForceTriad Energy Platform Front Panel



Introduction

The ForceTriad energy platform is designed to provide RF energy for monopolar and bipolar surgical applications and tissue-fusion applications. It features three touchscreen user interfaces, and has the ability to automatically detect handsets and configure the generator accordingly. Safety and diagnostic functionality include automatic fail-safe functions.

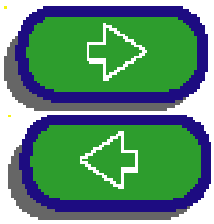
The Valleylab ForceTriad energy platform, patient return electrodes, and active instruments are designed to work as a system. Valleylab offers a selection of patient return electrodes and active instruments that are fully compatible with this energy platform. When considering other manufacturers' patient return electrodes and/or active instruments, customers should seek detailed user instructions and warning information from the manufacturer.

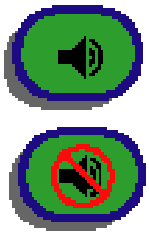
System Conventions

Touchscreens

The ForceTriad energy platform features a user-friendly interface with three touchscreens that allow the user to control system functions. The active touchscreen or touchscreens will illuminate, and the unavailable touchscreens will dim.

Common Symbols

Symbol	Name	Description
	Page Up/Page Down	Scroll through blocks of options that cannot be displayed on a single screen.
	Up/Down	Pressing once increases/decreases the associated value or moves highlighted selection up/down one line. Pressing and holding scrolls up/down.
	Next/Back	Progresses/regresses to the next screen.
	Back Space	Regresses one character.

Symbol	Name	Description
	Bipolar Mute On/Off	Turn on/off the audio tones produced by the system that indicate the increase or decrease of current during a bipolar procedure.
	Cancel	Cancels current screen and returns to the previous screen.
	Enter	Accepts and initiates current selections.
	System Tray	The system tray contains controls that allow you to access and adjust system settings including screen brightness and main menu options.
	Brightness	Each selection of this button adjusts the screen brightness to the next of the two available brightness settings. When maximum brightness is reached, next selection resets to the least bright setting.
	Wrench	Select access to the main menu, which provides user-selected options for language, appearance, and operation.
	Errors Disabled	This indicates that error warnings have been disabled using the service menu. The generator will not alarm or give error conditions when this symbol is activated.

Note: Additional information on symbols may be found in the *Technical Specifications* chapter in this manual.

Power Modes

As a safety feature to prevent unexpected power delivery spikes, simultaneous activation of multiple instruments is not possible on the ForceTriad energy platform.

Monopolar Modes

The ForceTriad energy platform produces five different modes of power output.

Cut Modes

Pure cut provides a clean, precise cut in any tissue with little or no hemostasis.

Blend cut is a conventional blended waveform that provides slower cutting and additional hemostasis.

Valleylab Mode

Valleylab mode is a unique combination of hemostasis and dissection and allows the user to slow down for more hemostasis and speed up for faster dissection. Thermal spread is equal or superior to Cut or Blend modes.

Coag Modes

Fulgurate coagulates tissue by sparking from the active electrode, through air, to the patient tissue. Since sparks may spray unpredictably from the electrode during fulguration, using fulguration for delicate tissue or in confined areas can complicate surgery. Accidental sparking to adjacent areas can occur as tissue at the surgical site dries and becomes more resistant to current flow.

Spray delivers wider fulguration; penetration is shallower and the affected tissue area is larger than with the Fulgurate mode.

Bipolar Modes

Three bipolar modes are available: Low, Standard, and Macrobipolar.

Low delivers precision and fine control over the amount of desiccation.

Standard is a conventional bipolar output at low voltage.

Macro (Macrobipolar) may be used for bipolar cutting or rapid coagulation. Power remains constant over a wide range of tissue types.

Autobipolar

The autobipolar feature senses tissue impedance between the two bipolar electrodes, then uses the impedance information to automatically start or stop bipolar RF energy delivery. Optionally, the user may choose between footswitch start and auto start, or program a delay between auto start and RF activation.

LigaSure Mode

The LigaSure tissue fusion mode can be used on arteries, veins, and lymphatics up to and including 7 mm in diameter and tissue bundles. This system provides precise energy delivery and electrode pressure to vessels for a controlled time period to achieve a complete and permanent fusion of the vessel lumen. The system has been designed to produce minimal sticking, charring, or thermal spread to adjacent tissue.

LigaSure Instruments

The LigaSure instruments that complete the ForceTriad tissue fusion system include multiple reusable and single use instruments for open and laparoscopic procedures. Each reusable instrument requires a corresponding single use electrode. The LigaSure function is only available when using Valleylab LigaSure instruments.

Chapter 2

Patient and Operating Room Safety

The safe and effective use of electrosurgery depends to a large degree upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant surgical team. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

Electrosurgery has been used safely in millions of procedures. Before starting any surgical procedure, the surgeon should be trained in the particular technique and surgical procedure to be performed, should be familiar with the medical literature related to the procedure and potential complications, and should be familiar with the risks versus the benefits of utilizing electrosurgery in the procedure.

General

Setting Up the System

Warning

Electric Shock Hazard Connect the system power cord to a properly grounded power receptacle. Do not use power plug adapters.

Fire Hazard Do not use extension cords.

Patient Safety Use the energy platform only if the power-up self-test has been completed as described in this manual, otherwise inaccurate power outputs may result.

Caution

When using a smoke evacuator in conjunction with the ForceTriad energy platform, set the system volume control at a level that ensures that the activation tones can be heard.

Connect only Valleylab-approved footswitches. Using footswitches from other manufacturers may cause equipment malfunction.

Warning

Hazardous Electrical Output This equipment is for use only by trained, licensed physicians.

Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use of this equipment without such training can result in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

Always use the lowest power setting that achieves the desired surgical effect. The active electrode should be utilized only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Accidental and unintended burn injury has occurred during procedures in small surgical fields and on small appendages. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.

Do not wrap the instrument cords or patient return electrode cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

Electric Shock Hazard Do not connect wet instruments to the energy platform. Ensure that all instruments and adapters are correctly connected and that no metal is exposed at any connection points.

Confirm proper power settings before proceeding with surgery. If the proper power settings are not known, set the power to a low setting and cautiously increase the power until the desired effect is achieved. If increased power settings are requested, check the patient return electrode and all instrument connections before major power setting adjustments.

Warning

Contact between the active electrode and any metal will greatly increase current flow and can result in unintended surgical effect.

While using electrosurgery, the patient should not be allowed to come into direct contact with grounded metal objects (e.g., surgical table frame, instrument table, etc.). If this is not possible during certain procedures (e.g., those in which noninsulated head frames are used), use extreme caution to maximize patient safety:

- Use the lowest power setting that achieves the desired effect.
- Place the patient return electrode as close to the surgical site as possible.
- Place dry gauze between the patient and the grounded object if possible.
- Continually monitor the contact point(s).
- Do not use metal needle monitoring electrodes.

Caution

Read all warnings, cautions, and instructions provided with this energy platform before using.

Read the instructions, warnings, and cautions provided with electrosurgical instruments before using. Specific instructions for electrosurgical instruments are not included in this manual.

For surgical procedures where the current could flow through delicate parts of the body, the use of bipolar techniques may be desirable in order to avoid unwanted coagulation.

Examine all instruments and connections to the system before using. Ensure that the instruments function as intended. Improper connection may result in arcs, sparks, instrument malfunction, or unintended surgical effects.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when the energy platform is delivering RF energy.

A non-functioning ForceTriad energy platform may cause interruption of surgery. A backup system should be available for use.

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical smoke evacuator or other means. [a]

Inadvertent activation may occur while installing, removing, or bending electrodes. Ensure that the instrument cord is not connected to the ForceTriad energy platform or that the system is OFF.

a. U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). Control of Smoke from Laser/Electric Surgical Procedures. HAZARD CONTROLS, Publication No. 96-128, September, 1996.

Notice

Connect the power cord to a properly grounded power receptacle having the correct voltage. Otherwise, product damage may result.

Important

If required by local codes, connect the energy platform to the hospital equalization connector with an equipotential cable.

Fire/Explosion Hazard

Warning

Danger: Explosion Hazard Do not use electrosurgery in the presence of flammable anesthetics.

Fire Hazard Do not place active instruments near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical instruments that are activated or hot from use can cause a fire. When not in use, place electrosurgical instruments in a safety holster or safely away from patients, the surgical team, and flammable materials.

Warning

Fire Hazard Sparking and heating associated with electrosurgery can be an ignition source. Keep gauze and sponges wet. Keep electrosurgical electrodes away from flammable materials and oxygen (O_2) enriched environments.

Use of electrosurgery in O_2 rich environments increases the risk of fire. Therefore, take measures to reduce the O_2 concentration at the surgical site.

Avoid enriched O_2 and nitrous oxide (N_2O) atmospheres near the surgical site. Both O_2 and N_2O support combustion and may result in fires and burns to patients or surgical personnel.

If possible, stop supplemental oxygen at least one minute before and during use of electrosurgery.

Do not activate the energy platform until flammable vapors from skin prep solutions and tinctures have dissipated.

Avoid the accumulation of naturally occurring flammable gases that may accumulate in body cavities such as the bowel.

Prevent pooling of flammable fluids and the accumulation of flammable or oxidizing gases or vapors under surgical drapes or near the surgical site.

Tissue buildup (eschar) on the tip of an active electrode may create embers that pose a fire hazard, especially in oxygen enriched environments. Keep the electrode clean and free of all debris.

Facial and other body hair is flammable. Water soluble surgical lubricating jelly may be used to cover hair close to the surgical site to decrease flammability.

Verify that all anesthesia circuit connections are leak free before and during use of electrosurgery.

Fire Hazard During Oropharyngeal Surgery

Verify endotracheal tubes are leak free and that the cuff seals properly to prevent oxygen leaks.

If an uncuffed tube is in use, pack the throat with wet sponges around the uncuffed tube, and be sure to keep sponges wet throughout the procedure.

Question the need for 100% O_2 during oropharyngeal or head and neck surgery.

If necessary, scavenge excess O_2 with separate suction.

Energy Platform

Warning

Each instrument receptacle on this energy platform is designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a receptacle. Doing so will cause simultaneous activation of the instruments. Follow the instructions provided with electrosurgical instruments for proper connection and use.

Caution

Do not stack equipment on top of the energy platform or place the energy platform on top of electrical equipment. This is an unstable configuration and does not allow for adequate cooling.

Caution

Provide as much distance as possible between the energy platform and other electronic equipment (such as monitors). Do not cross or bundle electronic device cords. This energy platform may cause interference with other electronic equipment.

Active instruments

Caution

Read the instructions, warnings, and cautions provided with electrosurgical instruments before using. Specific instructions for electrosurgical instruments are not included in this manual.

Inspect instruments and cords for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Damaged instruments or cords may result in injury or electrical shock to the patient or surgical team.

Use only instruments that can withstand the maximum output (peak) voltage for each output mode as listed in the *Technical Specifications* chapter in this manual. Using an instrument with a voltage rating that is lower than the maximum output voltage may result in injury to the patient or the operator, or damage to the instrument.

All Valleylab instruments have voltage ratings that are greater than the maximum output voltages in the ForceTriad energy platform and are thus fully compatible.

Information on voltage ratings for non-Valleylab instruments should be obtained from the instrument's manufacturer.

Pacemakers and ICDs

Warning

Use electrosurgery and tissue fusion with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital cardiology department for further information when use of electrosurgery or tissue fusion appliances is planned in patients with cardiac pacemakers.

If the patient has an implantable cardioverter defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical or tissue fusion procedure. Electrosurgery or tissue fusion may cause multiple activations of ICDs.

After Surgery

Warning

Electric Shock Hazard Always turn off and unplug the energy platform before cleaning.

Caution

Do not reprocess, reuse or resterilize instruments labeled “disposable” or “single use only.”

Notice

Do not clean the energy platform with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the energy platform.

Monopolar

Warning

Simultaneously activating suction/irrigation and electrosurgical current may result in increased arcing at the electrode tip, burns to unintended tissues, or shocks and burns to the surgical team.

Some surgeons may elect to “buzz the hemostat” during surgical procedures. It is not recommended, and the hazards of such a practice probably cannot be eliminated. Burns to the surgeon’s hands are possible. To minimize the risk take these precautions:

- Do not “buzz the hemostat” with a needle electrode.
- Do not lean on the patient, the table, or the retractors while buzzing the hemostat.
- Activate cut rather than coag. Cut has a lower voltage than coag.
- Firmly grasp as much of the hemostat as possible before activating the energy platform. This disperses the current over a larger area and minimizes the current concentration at the finger tips.
- “Buzz the hemostat” below hand level (as close as possible to the patient) to reduce the opportunity for current to follow alternate paths through the surgeon’s hands.
- Use the lowest power setting possible for the minimum time necessary to achieve hemostasis.
- Activate the energy platform after the instrument makes contact with the hemostat. Do not arc to the hemostat.
- When using a coated or nonstick blade electrode, place the edge of the electrode against the hemostat or other metal instrument.

Patient Return Electrodes

Warning

Do not attempt to use patient return electrodes that disable the REM system. The ForceTriad energy platform's REM system will function correctly only with contact quality monitoring (CQM) split-style patient return electrodes. Any other patient return electrode products may cause patient injury or product damage.

The safe use of monopolar electrosurgery requires proper placement of the patient return electrode. To avoid electrosurgical burns beneath the patient return electrode, follow all directions provided with the product.

Do not cut a patient return electrode to reduce its size. Patient burns due to high current density may result.

A patient return electrode is not necessary in bipolar or LigaSure procedures.

To avoid patient burns, ensure that the patient return electrode firmly and completely contacts the skin. Always check the patient return electrode periodically and after the patient is repositioned and during procedures involving long periods of activation.

Use of duty cycles greater than 25% (10 seconds active followed by 30 seconds inactive) will increase the risk that heat build-up under a return electrode may be high enough to injure the patient. Do not continuously activate for longer than one minute.

Notice

Capacitive pads and other non-CQM patient return electrodes may not work with the ForceTriad energy platform.

Important

A statement of compatibility from the CQM patient return electrode manufacturer should be obtained prior to the use of a non-Valleylab CQM patient return electrode.

Inadvertent Radio Frequency (RF) Burns

Warning

Electrodes and probes used with monitoring, stimulation, and imaging devices (or similar equipment) can provide a path for high frequency current even if the electrodes or probes are isolated at 50-60 Hz, insulated, and/or battery operated.

Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

To reduce the risk of an inadvertent electrosurgical burn at the electrode or probe site, place the electrode and/or probe as far away as possible from the electrosurgical site and/or patient return electrode. Protective impedances (resistors or RF inductors) installed in the monitoring leads may reduce the risk of such burns. Consult the hospital biomedical engineer for further information.

Warning

In some circumstances, the potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the patient return electrode that includes the skin-to-skin contact point. Current passing through small skin-to-skin contact points is concentrated and may cause a burn. This is true for ground referenced and isolated output electrosurgical energy systems.

To reduce the potential for alternate site burns, do one or more of the following:

- Avoid skin-to-skin contact points, such as fingers touching leg or knee touching knee when positioning the patient.
- Place insulation, such as dry gauze or towel, between contact points to ensure that contact does not occur.
- Position the patient return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas.
- In addition, place patient return electrodes according to the manufacturer's instructions.

Bipolar

Caution

Bipolar instruments must be connected to the bipolar instrument receptacle only. Improper connection may result in inadvertent system activation.

LigaSure

Warning

LigaSure instruments are intended for use ONLY with the Valleylab ForceTriad energy platform and the Valleylab LigaSure vessel sealing system. Use of these instruments with other Valleylab generators or with generators produced by other manufacturers may not result in electrical output for which these instruments were designed and thus may not result in the desired clinical effect.

If the seal cycle complete tone has not sounded, an optimal seal may not have been achieved. Reactivate the RF energy until a seal complete tone is heard.

The LigaSure tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

Use caution during surgical cases in which patients exhibit certain types of vascular pathology (atherosclerosis, aneurysmal vessels, etc.). For best results, apply the seal to unaffected vasculature.

Do not activate the energy platform in the LigaSure mode until the tissue fusion instrument has been applied with the proper pressure. Activating the energy platform before this is done will result in an improper seal and may increase thermal spread to tissue outside the surgical site.

Warning

Tissue fusion requires the application of RF energy and pressure from the instrument. Tissue to be sealed must be firmly grasped between the instrument jaw electrodes. Tissue in the jaw hinge or outside the instrument jaw will not be sealed even if thermal blanching occurs.

Do not use LigaSure instruments on vessels in excess of 7 mm in diameter.

LigaSure instruments that require single use electrodes must be used with the correct electrode type. Use of these instruments with any other electrodes could result in injury to the patient or surgical team, or cause damage to the instrument.

Conductive fluids (e.g, blood or saline) in direct contact with LigaSure instruments or in close proximity may carry electrical current or heat, which may cause unintended surgical effects or burns.

Caution

Energy based devices, such as electrosurgical pencils or ultrasonic scalpels, that are associated with thermal spread should not be used to transect seals.

Avoid placing fingers in the handle ratchet mechanism. Injury to the user may result.

LigaSure in Laparoscopic Procedures

Warning

For laparoscopic procedures, be alert to these potential hazards:

- The external surfaces of the LigaSure instrument jaws may remain hot enough to cause burns after the RF current is deactivated.
- Inadvertent activation or movement of the activated LigaSure instrument outside of the field of vision may result in injury to the patient.
- Do not activate the instrument while the instrument jaws are in contact with, or in close proximity to, other instruments including metal cannulas, as localized burns to the patient or physician may occur.
- Do not activate the LigaSure function in an open circuit condition. Activate the energy platform only when the instrument is near or in direct contact with the target tissue to reduce the possibility of unintended burns.
- Carefully insert and withdraw LigaSure instruments from cannulas to avoid possible damage to the devices and/or injury to the patient.

Servicing

Warning

Electric Shock Hazard Do not remove the energy platform cover. Contact authorized personnel for service.

Notice

Refer to this system's service manual for maintenance recommendations and function and output power verification procedures.

Shunt Cords

Warning

Some surgical instruments (e.g., colonoscopes) may allow substantial leakage current that could burn the surgeon. If the instrument manufacturer recommends the use of a shunt cord (s-cord) to direct the current back to the energy platform, you must also use a Valleylab E0507-B adapter. To avoid a REM alarm, you must use a REM patient return electrode with the E0507-B adapter.

Procedures Where Conductive Fluid is Introduced into the Surgical Site

Warning

When this energy platform is used in procedures where conductive fluid (saline or lactated Ringers) is introduced into the surgical site for distention or to conduct RF current, higher than normal currents (greater than one amp) may be produced. In this situation, use one or more **adult**-size return electrodes. Do not use return electrodes labeled for children, infants, babies, neonatal use, or pediatric use.

Use of duty cycles greater than 25% (10 seconds active followed by 30 seconds inactive) will increase the risk that heat build-up under a return electrode may be high enough to injure the patient. Do not continuously activate for longer than one minute.

Laparoscopic Procedures

Warning

For laparoscopic procedures, be alert to these potential hazards:

- Laparoscopic surgery may result in gas embolism due to insufflation of gas in the abdomen.
- The electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of the activated electrode outside of the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrical currents carried through conductive objects (such as cannulas or scopes). Electrical current may be generated in conductive objects through direct contact with the active electrode, or by the active instrument (electrode or cable) being in close proximity to the conductive object.
- Do not use hybrid trocars that have a non-conductive locking anchor placed over a conductive sleeve. For the operative channel, use all metal or all plastic systems. At no time should electrical energy pass through hybrid systems. Capacitive coupling of RF current may cause unintended burns.
- When using laparoscopic instrumentation with metal cannulas, the potential exists for abdominal wall burns to occur due to direct electrode contact or capacitive coupling of RF current. This is most likely to occur in instances where the energy platform is activated for extended periods at high power levels inducing high current levels in the cannula.
- Ensure that the insulation of single use and reusable laparoscopic instrumentation is intact and uncompromised. Compromised insulation may lead to inadvertent metal-to-metal sparking and neuromuscular stimulation and/or inadvertent sparking to adjacent tissue.
- Do not activate electrodes while in contact with other instruments as unintended tissue injury may occur.

Do not activate the energy platform in an open circuit condition. To reduce the chances of unintended burns, activate the energy platform only when the active electrode is near or touching the target tissue.

- Use the lowest power setting that achieves the desired surgical effect and use a low voltage waveform (Pure Cut, Blend, or Valleylab mode) to lessen the potential for the creation of capacitive currents.
- Carefully insert and withdraw active electrodes from cannulas to avoid possible injury to the patient or damage to the devices.

Valleylab recommends against the use of laparoscopic surgery on pregnant patients.

Chapter 3

System Setup

This chapter describes the how to set up the energy platform, turn it on, and configure system settings.

Caution
Read all warnings, cautions, and instructions provided with this system before use.
Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions for electrosurgical instruments are not included in this manual.

Setup

Before Startup

1. Verify the system is off by pressing the power switch off (O).
2. Place the energy platform on a flat, stable surface such as a table, platform, boom system, or Valleylab cart. Carts with conductive wheels are recommended. Refer to the procedures for your local institution or your local codes.
3. Plug the system power cord into the rear panel receptacle.
4. Plug the system power cord into a grounded power receptacle.

   Note: Do not plug into a power strip or extension cord.

Powering Up the ForceTriad Energy Platform

1. Turn on the system by pressing the power switch on (|). Observe the following during the power-up self test:
   - The ForceTriad logo will appear on all three screens.
   - A status bar indicates activity.
   - An hourglass icon indicates activity after the status bar disappears.
   - A tone will sound upon completion of self-test.
2. If the system does not pass the power-up self test, refer to Chapter 7, *Troubleshooting*.

System Functions

Adjusting Display Brightness

The ForceTriad energy platform screens have two levels of brightness. Touch the brightness icon on the right side of the right touchscreen to adjust the display brightness.

Activation Log

The Activation Log allows the user to view the last 1000 activations and REM alerts.

1. Touch the wrench icon on the right side of the right touchscreen. The main menu display will appear in the left touchscreen.
2. Touch Activation Log in the main menu. The activation log will appear on the center touchscreen.
3. Touch the single up or down arrows to the right of the activation log to scroll through the log one line at a time.
4. Touch the green arrow button on the bottom right corner of the main menu screen to return the ForceTriad energy platform to the previous setup configuration. The last settings will be displayed.

Service Display

Refer to the ForceTriad energy platform service manual for complete service instructions.

Restore

Select the Restore button in the main menu to restore the ForceTriad energy platform to the previous setup configuration. The touchscreens will display the last settings entered prior to shutting the system off.

Setup

The setup menu allows the user to change the language that the system touchscreens display, set the time and date, and enable or disable the Autobipolar mode.

Language Setup

1. Touch the wrench icon on the right side of the right touchscreen. The main menu display will appear in the left touchscreen.
2. Touch Setup in the main menu. The setup display will appear in the left touchscreen.
3. Touch Language in the setup menu. A list of languages will appear in the left touchscreen.
4. Touch the single up or down arrows to the right of the list to scroll through the list one line at a time.

   or

   Touch the double up or down arrows to scroll through the list one page at a time.
5. Touch the desired language. A confirmation box will appear and request the user to confirm that a language change is desired.
6. To proceed with the language change, touch the green check mark button. The language will be activated and the confirmation box will close.

   or

   To reject the language change, touch the red ‘X’ button. The language setting will return to the previously selected language.
7. Touch the green arrow button to return to the setup menu.
8. Touch the green arrow button below the setup menu to return to the main menu.

Time and Date Setup

1. Touch the wrench icon on the right side of the right touchscreen. The main menu display will appear in the left touchscreen.
2. Touch Setup in the main menu. The setup display will appear in the left touchscreen.
3. Touch the Time and Date button in the setup menu. The time and date display will appear in the left touchscreen.
4. Touch the desired numeric field (minutes, seconds, month, day, or year) to select that field.
5. Touch the up or down arrows next to the time or date row to adjust the selected numeric field.

   Touch and hold the arrows to increase the number once per second. After four seconds, the numbers will increase once per 100 milliseconds.
6. Touch the green check mark button to store the date and time information and return to the setup menu.

   or

   Touch the red 'X' button to return the time and date to the previous settings and return to the setup menu.
7. Touch the green arrow button below the setup menu to return to the main menu.

Enable/Disable Autobipolar

1. Touch the wrench icon on the right side of the right touchscreen. The main menu display will appear in the left touchscreen.
2. Touch Setup in the main menu. The setup menu will appear in the left touchscreen.
3. If the Autobipolar mode is not enabled, the Autobipolar button will display 'Enable Autobipolar'. Touch the Enable Autobipolar button to enable the Autobipolar mode.

   If the Autobipolar mode is enabled, the Autobipolar button will display 'Disable Autobipolar'. Touch the Disable Autobipolar button to disable the Autobipolar mode.
4. Touch the green arrow button below the setup menu to return to the main menu.

Demo Mode

Warning

Demo mode is intended for demonstration purposes only. Demo mode is not intended for clinical use.

Touch the wrench icon on the right side of the right touchscreen. The main menu display will appear in the left touchscreen.

Enable Demo Mode

1. In the main menu, the Demo mode button will display ‘Enter Demo’ if the system is not in Demo mode. Touch the Enter Demo mode button to begin Demo mode. The system operating displays will appear in all the touchscreens with the words ‘DEMO MODE: Not for Clinical Use’ on all three screens.

   Note: Touching the Demo mode screen will remove it briefly from all touchscreens.

2. Proceed with any practice or demonstration scenarios. While in Demo mode, the REM alarm and the dual instrument error alarm are deactivated but RF power will still be delivered.

   Note: In Demo mode the generator will not sense instrument type, so the appropriate tab must be selected manually for the connected instrument.

3. To exit Demo mode, either turn the system off and restart it, or follow the steps in the *Exit Demo Mode* section as follows.

Exit Demo Mode

1. Touch the wrench icon on the right side of the right touchscreen. The main menu display will appear in the left touchscreen.
2. In the main menu, the Demo mode button will display ‘Exit Demo’ if the system is in Demo mode. Touch the Exit Demo button in the main menu to exit the Demo mode. The system touchscreens will display the last settings entered during the Demo mode.

Chapter 4

Monopolar Function

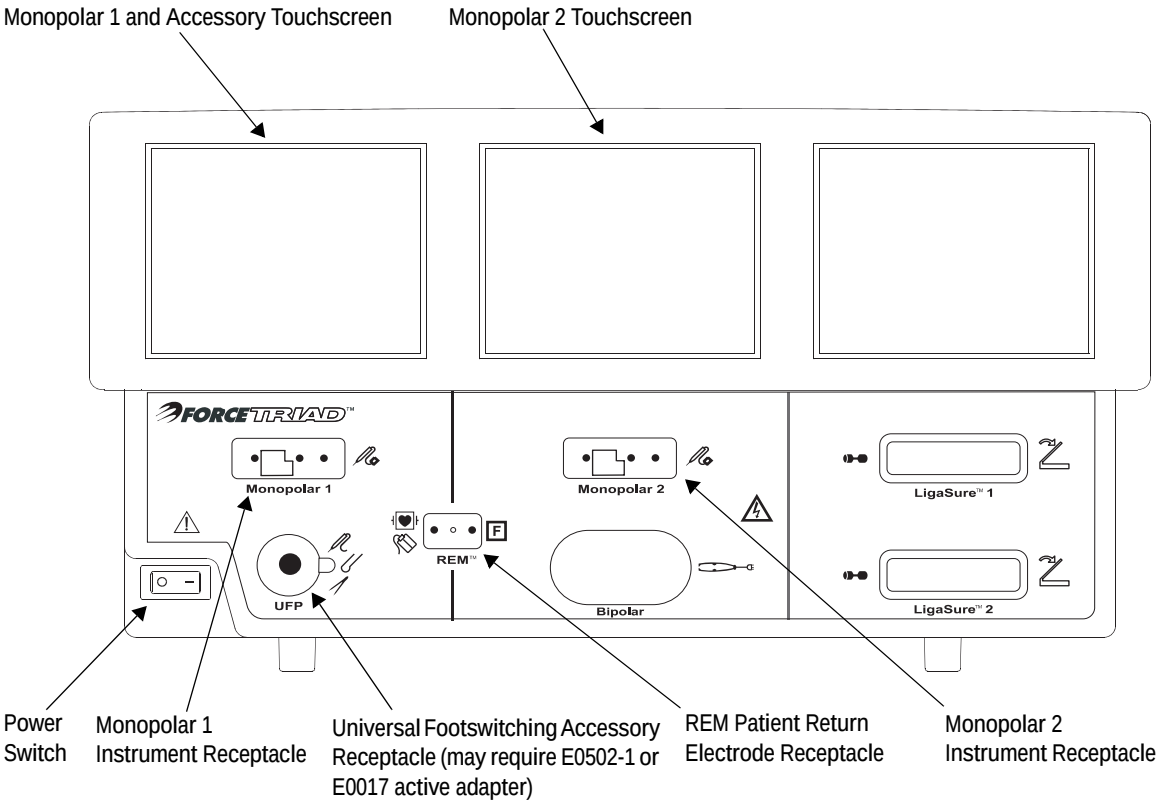
This chapter describes the monopolar surgery features of the ForceTriad energy platform.

Caution

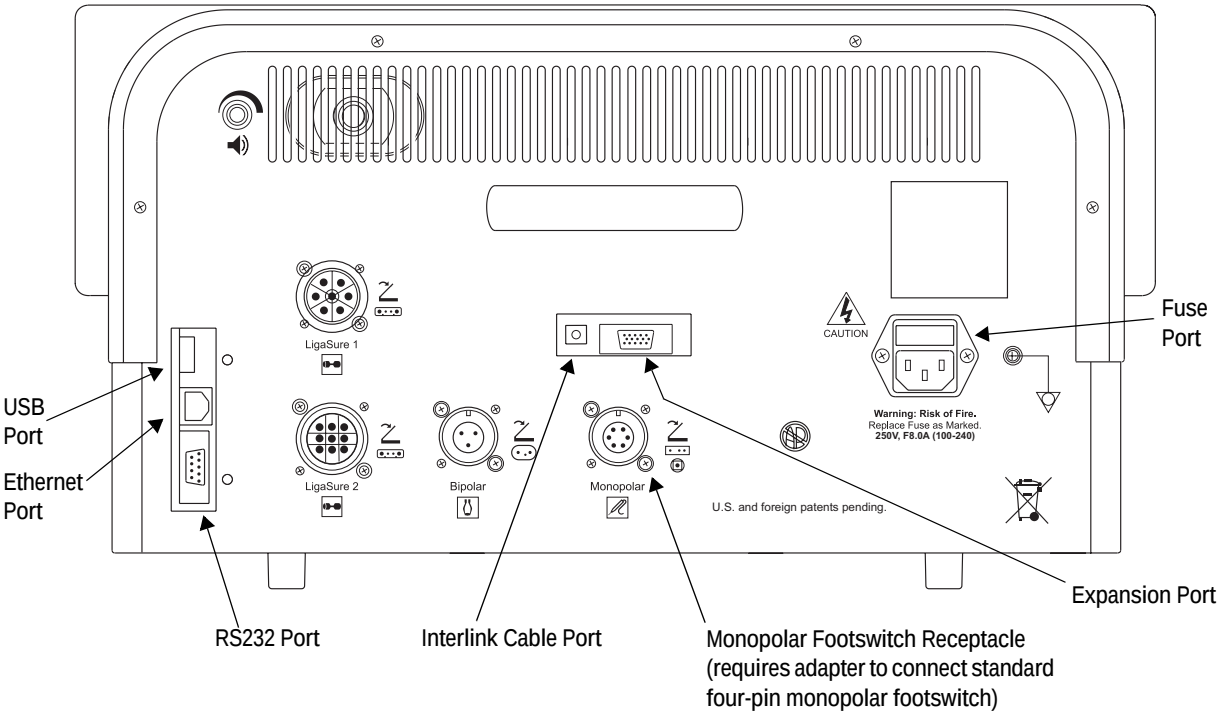
Read all warnings, cautions, and instructions provided with this system before use.

Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions for electrosurgical instruments are not included in this manual.

Front Panel Monopolar Features



Rear Panel Monopolar Features



Monopolar Quick Setup Instructions

If you are familiar with the ForceTriad energy platform, you may follow this abbreviated procedure to set up the system for monopolar surgery.

If you are not familiar with the ForceTriad energy platform, refer to the following sections in this chapter for detailed instructions.

1. Plug the system power cord into the rear panel receptacle.
2. Plug the system power cord into a grounded power receptacle.
3. Turn on the energy platform and verify that the self-test is successfully completed.
4. If using a footswitch, connect it to the monopolar footswitch receptacle on the rear panel. This may require an adapter to connect a standard four-pin monopolar footswitch.
5. Apply the patient return electrode to the patient and connect it to the patient return electrode receptacle on the front panel.
6. Connect the instrument to the appropriate instrument receptacle on the front panel.
7. Verify or change the mode and power settings.

Monopolar Function Overview

Monopolar Power Output Modes

The ForceTriad energy platform produces two cut modes, Pure and Blend; one Valleylab mode; and two coag modes, Fulgurate and Spray.

Warning

Electric Shock Hazard

- Do not connect wet instruments to the system.
- Ensure that all instruments and adapters are correctly connected and that no metal is exposed at any connection point.

Connect instruments to the proper receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with electrosurgical instruments for proper connection and use.

The instrument receptacles on this energy platform are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

Caution

Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions are not included in this manual.

Inspect instruments and cords (especially reusable instruments and cords) for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

Monopolar Footswitch

The ForceTriad energy platform in the monopolar mode can accommodate a monopolar footswitch when used with the accompanying adapter. This monopolar footswitch controls only those instruments connected to the accessory receptacle controlled by the left panel.

If you plan to use a footswitching monopolar instrument, attach the monopolar footswitch adapter to the monopolar footswitch receptacle on the rear of the system.

Caution

Connect only Valleylab-approved footswitches. Using footswitches from other manufacturers may cause equipment malfunction.

Return Electrodes – REM Contact Quality Monitoring System

Notice

Only contact quality monitoring system patient return electrodes can be used with the ForceTriad energy platform.

Patient Return Electrode Considerations

During monopolar electrosurgery, a patient return electrode is always required to safely recover the current that flows through the patient's body and return it to the energy platform. A reduction in surface area contact or poor conductivity between the patient and the return electrode can cause the current to become concentrated, potentially resulting in burns at the return electrode site.

During a surgical procedure, the amount of current delivered during a given time period determines the amount of heating that occurs under the return electrode. Valleylab REM patient return electrodes are designed for use during conventional electrosurgical procedures and duty cycles (on time compared to off time). Users should consult the *Technical Specifications* chapter in this manual for the recommended maximum duty cycle specifications.

It is not possible to foresee what combination of current and duty cycle may be safely used in every situation, such as when higher currents and/or longer duty cycles are used on procedures such as tissue lesioning, tissue ablation, tissue vaporization, and procedures where conductive fluid is introduced into the surgical site. Under these conditions a greater risk may exist that the heating under a fully applied return electrode may be high enough to injure the patient. When using a Valleylab energy platform or a patient return electrode during these types of surgical procedures, the user should seek written guidance in the form of detailed user instructions from the manufacturer of the active accessory regarding the currents and duty cycles that can be expected. In some instances, the application of additional patient return electrodes may help mitigate the increased risk.

How the REM System Works

The ForceTriad energy platform uses the Valleylab REM contact quality monitoring system to monitor the quality of electrical contact between the patient return electrode and the patient. The REM system is designed to reduce the risk of burns at the return electrode site. A non-REM return electrode is not to be used with the ForceTriad energy platform.

The REM system continuously measures the resistance at the return electrode site and compares it to a standard range of safe resistance (between 5 and 135 ohms), thus eliminating intermittent false alarms that could result from small changes in resistance. The REM system also adapts to individual patients by measuring the initial contact resistance between the patient and the patient return electrode and lowering the baseline resistance if the contact resistance drops.

A REM alarm sounds and the system stops producing output power when **either** of the following occurs:

- The measured resistance is below 5 ohms or above 135 ohms, the limits of the standard range of safe resistance.
- An increase in contact resistance is greater than 40% from the baseline measurement.

Patient Return Electrode Setup

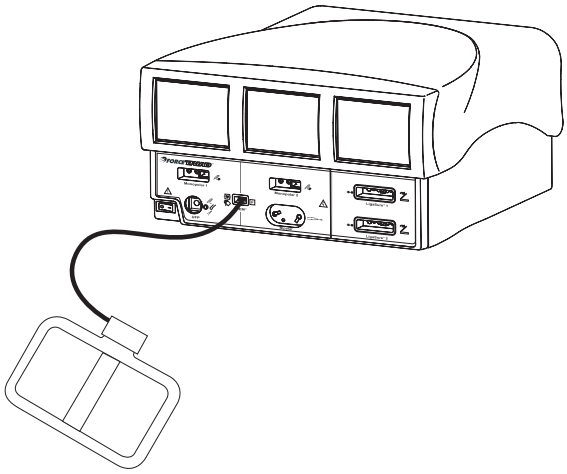
The REM indicator icon appears on the Standard Monopolar, Valleylab, and Accessory Port displays.

Warning

The safe use of monopolar electrosurgery requires proper placement of the patient return electrode. To avoid electrosurgical burns beneath the patient return electrode, follow all directions on the product package for proper return electrode placement and use.

Do not cut a patient return electrode to reduce its size. Patient burns due to high current density may result.

1. Place the patient return electrode on the patient. Refer to the patient return electrode instructions for proper return electrode placement.
2. Connect the REM patient return electrode plug to the patient return electrode receptacle on the energy platform.

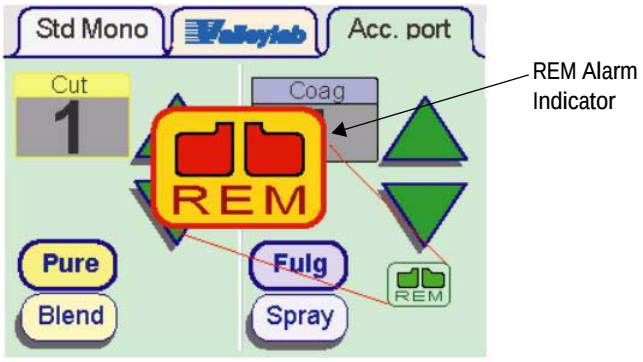


The REM indicator icon on the touchscreen illuminates red to indicate that the REM patient return electrode is disconnected from the energy platform or improperly applied to the patient.

The REM indicator icon on the touchscreen illuminates green when the system senses that the REM patient return electrode is properly connected to the energy platform and patient.

REM Alarm (Visual and Audible)

If the REM system senses an alarm condition, the REM indicator flashes red and yellow, emits two beeps, and discontinues RF energy delivery. When the alarm condition has been corrected, the indicator illuminates green. Refer to the *Troubleshooting* chapter for detailed instructions on correcting REM alarms.



When a REM alarm occurs, the large red and yellow REM icon is displayed for a few seconds and then disappears. The small green REM icon turns red.

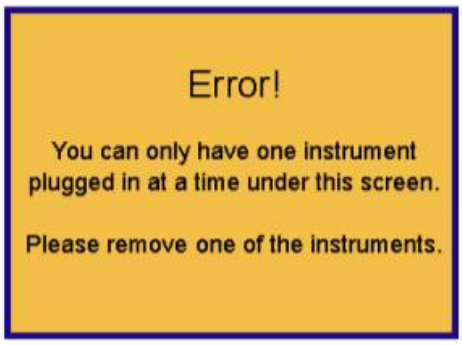
Active Electrodes

Connect a monopolar instrument to the Monopolar 1 or Monopolar 2 instrument receptacle on the front of the energy platform.

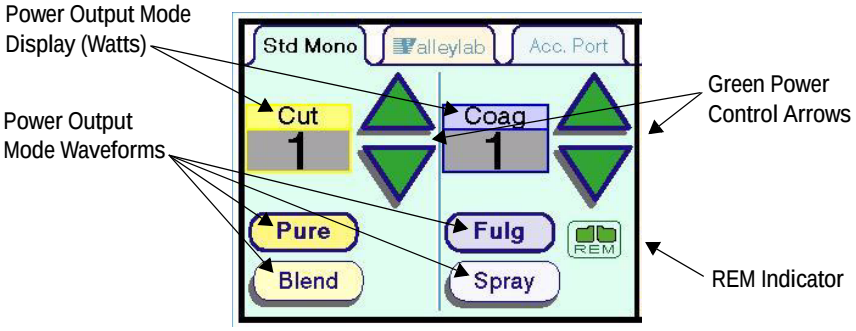
If a two-button instrument is connected to the energy platform, proceed to the *Standard Monopolar Mode Functionality* section below.

If a Valleylab mode enabled three-button instrument is connected to the energy platform, proceed to the *Valleylab Mode Functionality* section below.

Note: The Monopolar 1 and Monopolar 2 touchscreens can each control only one instrument at one time. If more than one instrument is attached under one touchscreen, the error message pictured below will display in the touchscreen. Both devices will be inactivated until one of the devices is removed.



Standard Monopolar Mode Functionality



When a two-button electrosurgical instrument is attached to either the Monopolar 1 or Monopolar 2 receptacle, the ForceTriad energy platform detects the instrument type and displays the Standard Monopolar tab on the touchscreen. The Standard Monopolar tab allows the user to control the power mode and power output level at the energy platform interface.

1. Select the power output mode waveform by pressing the associated button at the bottom of the tab. The waveforms available in the cut mode are Pure and Blend. In the coag mode, the waveforms available are Fulgurate or Spray.
2. Set the power to the desired output level by pressing either the green up or down arrows. Power output is displayed in watts.

3. Activate the cut mode by pressing the yellow button on the electrosurgical instrument. The cut display will illuminate yellow and a tone will sound for the duration of the activation.

   Activate the coag mode by pressing the blue button on the electrosurgical instrument. The coag display will illuminate blue and a tone will sound for the duration of the activation.

Valleylab Mode Functionality

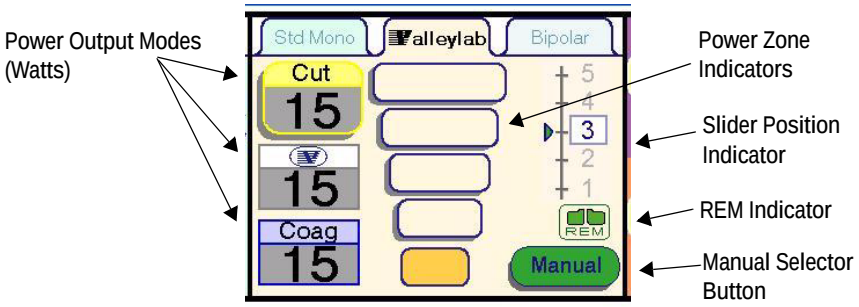
Valleylab instruments featuring the Valleylab mode are specialty devices that enable the surgeon to control ForceTriad energy platform output from the sterile field.

Three output modes are selected at the handset with the following buttons:

- The yellow cut button enables a cutting function.
- The clear Valleylab button enables a hemostasis function while providing dissection.
- The blue coag button enables a coagulation function.

A dual slider control switch adjusts power output in all three modes.

When a Valleylab mode instrument's Smart connector is attached to either the Monopolar 1 or Monopolar 2 receptacle, the ForceTriad energy platform detects the instrument type and displays the Valleylab tab on the corresponding touchscreen.



Power Zones: The five gold bars in the center of the Valleylab tab represent the five power zones available for the particular instrument attached to the energy platform receptacle. The system automatically selects the default power zone setting for the particular instrument. Power zones can only be changed at the touchscreen interface on the energy platform.

Note: Refer to the individual instrument instructions for power zone output in watts.

Slider Position: The energy platform detects the current position of the instrument's slider switch, and the slider position indicator on the right side of the Valleylab tab displays this slider position. Slider position can only be changed by the instrument user in the sterile field.

Using a Valleylab Mode Instrument

1. Select the desired power zone by touching the corresponding bar on the Valleylab tab touchscreen. The bar that was touched, along with all the bars below it, will illuminate gold and a brief double tone will sound. Power output is displayed in watts. The power zone cannot be changed during instrument activation.

Warning

The slider switch increases and decreases power output. Verify slider position prior to activation.

2. Activate power output by pressing the desired button on the instrument.
   - Activate the cut mode by pressing the yellow button on the electrosurgical instrument. The cut display will illuminate yellow and a tone will sound for the duration of the activation.
   - Activate the Valleylab mode by pressing the *clear* button on the electrosurgical instrument. The Valleylab display will illuminate white and a tone will sound for the duration of the activation.
   - Activate the coag mode by pressing the blue button on the electrosurgical instrument. The coag display will illuminate blue and a tone will sound for the duration of the activation.
3. Change power output within the selected zone by adjusting the slider position on the electrosurgical instrument. A double tone will sound when slider position is changed. Slider position can not be changed while RF energy is being delivered.

Cut Mode Disable

As a safety feature, power output can be disabled in the cut mode.

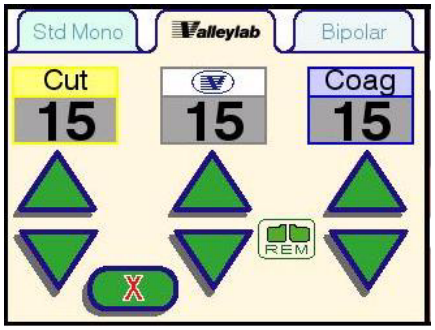
1. Disable the cut mode by pressing the yellow cut output mode display box. A '--' will replace the numeric digits in the cut box.
2. Re-enable the cut mode by pressing the yellow cut output mode display box. The cut box will display the power setting of the current instrument slider position. The cut mode is also re-enabled when the energy platform is restarted.

Manual Power Control Functionality

The manual mode allows the user to operate the energy platform outside the pre-set power ranges available in the Valleylab tab. In manual mode, the slider on the electrosurgical instrument is disabled, and power can only be set at the touchscreen interface.

1. To set the system into the manual mode, press the green Manual button

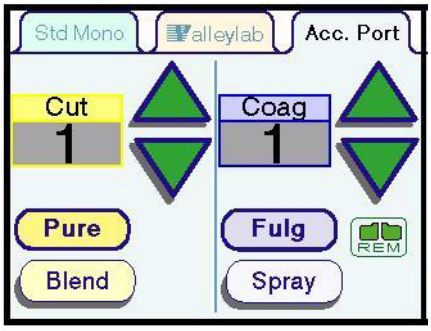
on the Valleylab tab touchscreen. The manual control display will appear on the touchscreen.



2. Adjust the power output for cut, Valleylab mode, and coag by pressing the associated green up or down buttons on the energy platform touchscreen.
3. To return to the sterile field control mode, click on the **X** button. The Valleylab mode control screen will re-appear on the touchscreen, and the power zone and slider position will reset based on the current instrument configuration.

Accessory Port Functionality

Instruments with 8 mm pins connect directly to the accessory port on the ForceTriad energy platform. Instruments with pin diameters less than 8 mm require the use of an E0502-1 or E0017 Valleylab adapter. Remove the adapter when not in use.



When a single pin electrosurgical instrument is attached to the universal footswitching accessory port, the ForceTriad energy platform detects the instrument and displays the Accessory Port tab on the touchscreen. The Accessory Port tab allows the user to control the power mode and power output level at the system interface for any footswitching instrument connected.

1. Select the power output mode waveform by pressing the associated button. The waveforms available in the cut mode are Pure and Blend. In the coag mode, the waveforms available are Fulgurate or Spray.
2. Set the power to the desired output level by pressing the green up and down arrows. Power output is displayed in watts.
3. Activate the cut mode by stepping on the cut or yellow pedal on the footswitch. The cut display will illuminate yellow and a tone will sound for the duration of the activation.

   Activate the coag mode by stepping on the coag or blue pedal on the footswitch. The coag display will illuminate blue and a tone will sound for the duration of the activation.

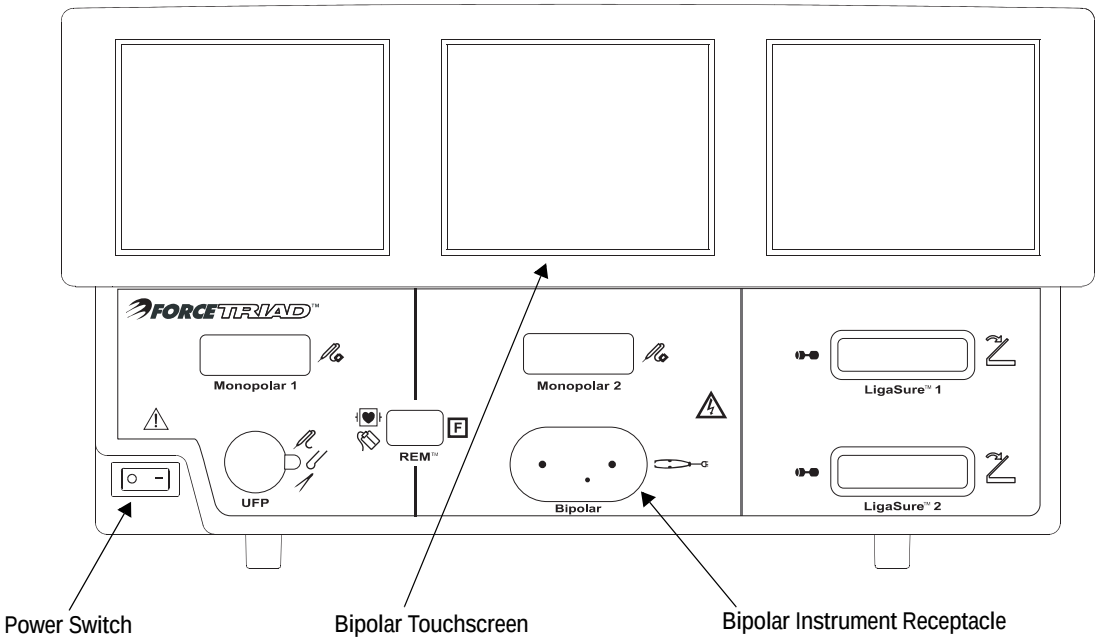
Chapter 5

Bipolar Surgery

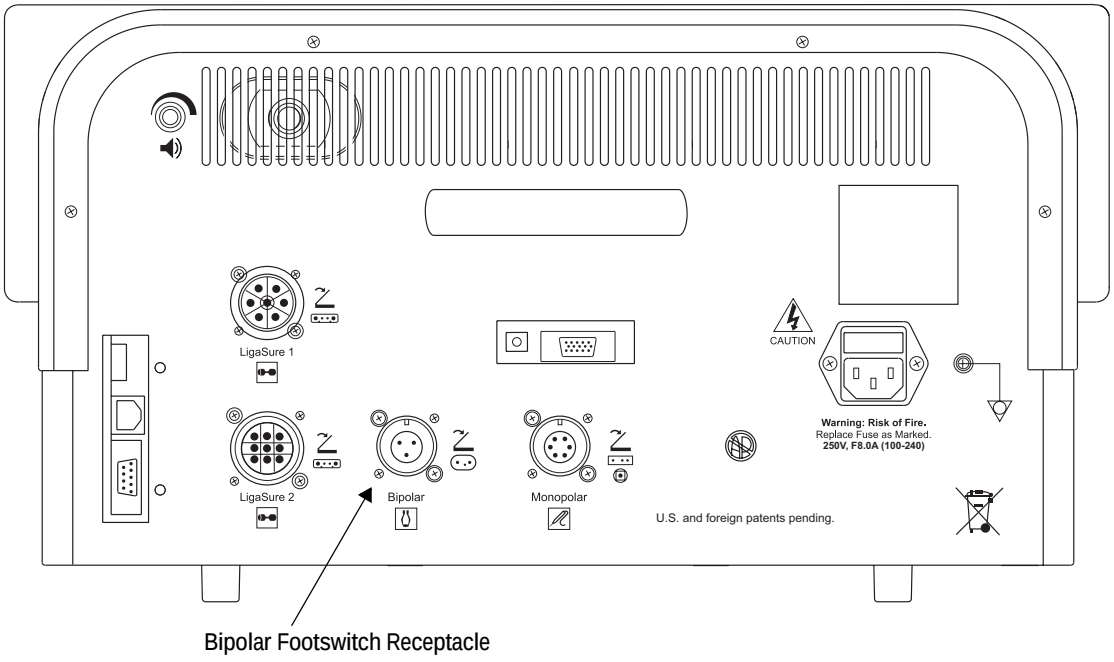
This chapter describes the bipolar surgery features of the ForceTriad energy platform.

Caution
Read all warnings, cautions, and instructions provided with this system before use.
Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions for electrosurgical instruments are not included in this manual.

Front Panel Bipolar Features



Rear Panel Bipolar Features



Bipolar Quick Setup Instructions

If you are familiar with the ForceTriad energy platform, you may follow this abbreviated procedure to set up the system for bipolar surgery.

If you are not familiar with the ForceTriad energy platform, refer to the following sections in this chapter for detailed instructions.

1. Plug the system power cord into the rear panel receptacle.
2. Plug the system power cord into a grounded wall receptacle.

   Note: Do not plug into a power strip or extension cord.
3. Turn on the system and verify that the self-test is successfully completed.
4. If using a footswitch, connect it to the bipolar footswitch receptacle on the rear panel.
5. Connect the instrument to the bipolar instrument receptacle on the front panel.
6. Verify or change the mode and power settings.

Bipolar Function Overview

Delicate tissue requires less energy to desiccate. The ForceTriad energy platform provides low voltage, continuous current for faster dessication without sparking.

The possibility of sparking increases as desiccated tissue dries and becomes more resistant to energy flow. The system protects against sparking by limiting the bipolar voltage at relatively high levels of tissue resistance.

Bipolar Power Output Modes

The ForceTriad energy platform produces three bipolar modes, Low, Standard, and Macro.

Warning

Electric Shock Hazard

- Do not connect wet instruments to the energy platform.
- Ensure that all instruments and adapters are correctly connected and that no metal is exposed at any connection point.

Connect instruments to the proper receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with electrosurgical instruments for proper connection and use.

The instrument receptacles on this system are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

Caution

Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions are not included in this manual.

Caution

Inspect instruments and cords (especially reusable instruments and cords) for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

Footswitch

The ForceTriad energy platform in bipolar mode can accommodate a three-pin, single-pedal bipolar footswitch.

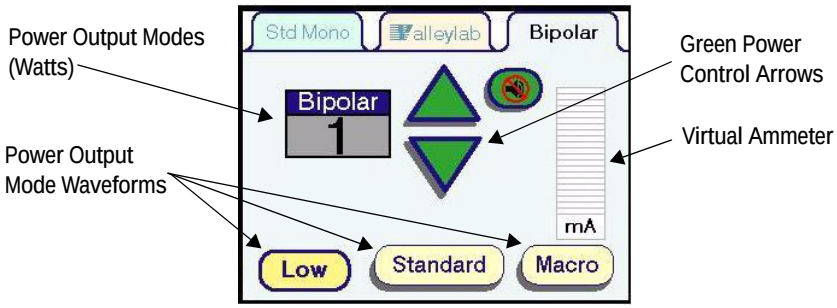
If you plan to use a footswitching bipolar instrument, attach the bipolar footswitch connector plug to the bipolar footswitch receptacle on the rear panel.

Bipolar Electrode Function

1. Connect a bipolar instrument to the bipolar instrument receptacle on the front panel.

   Note: The Bipolar touchscreen can control only one instrument at one time. If more than one instrument is attached under this touchscreen, an error message will display in the touchscreen. Both devices will be inactivated until one of the devices is removed.

   When a bipolar instrument is connected, the bipolar tab displays on the center touchscreen.



2. Select the power output mode waveform by pressing the associated button at the bottom of the tab. The waveforms available in the bipolar mode are Low, Standard, and Macro.
3. Set the power to the desired output level by pressing the green up and down arrows. Power output is displayed in watts.
4. Activate the bipolar mode by closing the forceps firmly or by stepping on the single-pedal footswitch. An activation tone will sound, and delivered current is displayed on the virtual ammeter.

Virtual Ammeter

The virtual ammeter on the bipolar tab displays the current being delivered during bipolar instrument activation. The ammeter registers current between 1 and 1050 milliamps. An audio tone sounds to indicate increases and decreases in current delivery. A mute button allows the user to silence the ammeter tone but not the activation tone.

Autobipolar Electrode Function

The ForceTriad energy platform is equipped with an autobipolar feature that allows the user to configure the system for automatic activation and cessation of bipolar energy.

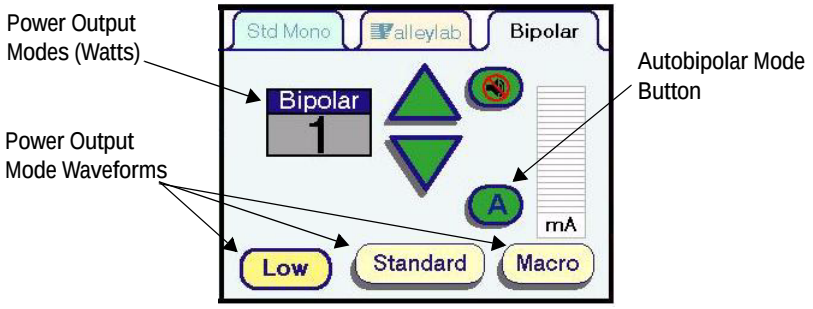
The Autobipolar mode must be enabled in the system setup menu before the autobipolar function can be used. Refer to the *System Setup* chapter for instructions on how to enable the Autobipolar mode.

When the Autobipolar mode has been enabled, a green button with an "A" will appear on the Bipolar tab.

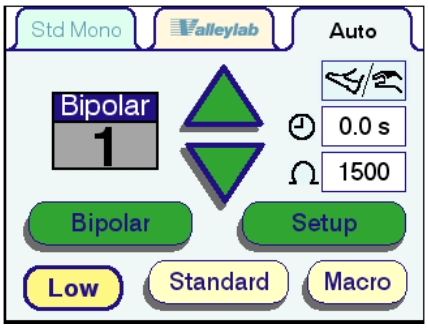
Note: The autobipolar electrode function requires the use of the Valleylab E0018 bipolar instrument cord.

Warning

Use of other Valleylab bipolar cords or cords produced by other manufacturers may not result in electrical output for which these instruments were designed and thus may not result in the desired clinical effect.

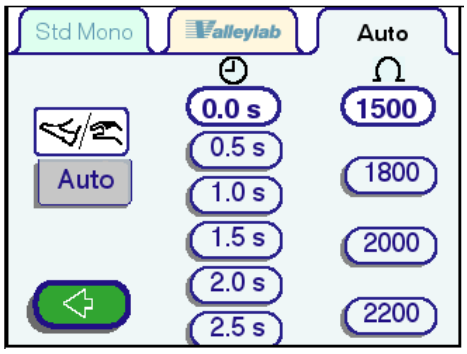


1. Press the Autobipolar mode button. The tab title will change from Bipolar to Auto, and the screen below will appear.



2. Select the power output mode waveform by touching the associated button at the bottom of the tab. The waveforms available in the Autobipolar mode are Low, Standard, and Macro.
3. Set the power to the desired output level by touching the green up and down arrows. Power output is displayed in watts.
4. To change the autobipolar activation parameters, touch the green Setup button.

The setup display will appear in the autobipolar tab.



5. To enable RF activation without needing to depress the footswitch, touch the Auto button.

   or

   To restrict RF activation to the footswitch, touch the footswitch/handswitch button.
6. Set the desired RF output delay by touching one of the six delay times available under the timer symbol.
7. Set the desired impedance level at which RF energy will be discontinued by touching one of the four impedance values under the impedance symbol.
8. Touch the green back arrow button to return to the autobipolar activation display. The settings selected in the setup display will appear in the autobipolar display.
9. Activate autobipolar by closing the instrument forceps tines firmly or by stepping on the single-pedal footswitch. An activation tone will sound.
10. To return the energy platform to bipolar functionality, touch the green Bipolar button. The bipolar tab will replace the autobipolar tab.

    or

    Turn the system off. The next time the system is turned on, it will default to the bipolar function, and the bipolar tab will be visible.

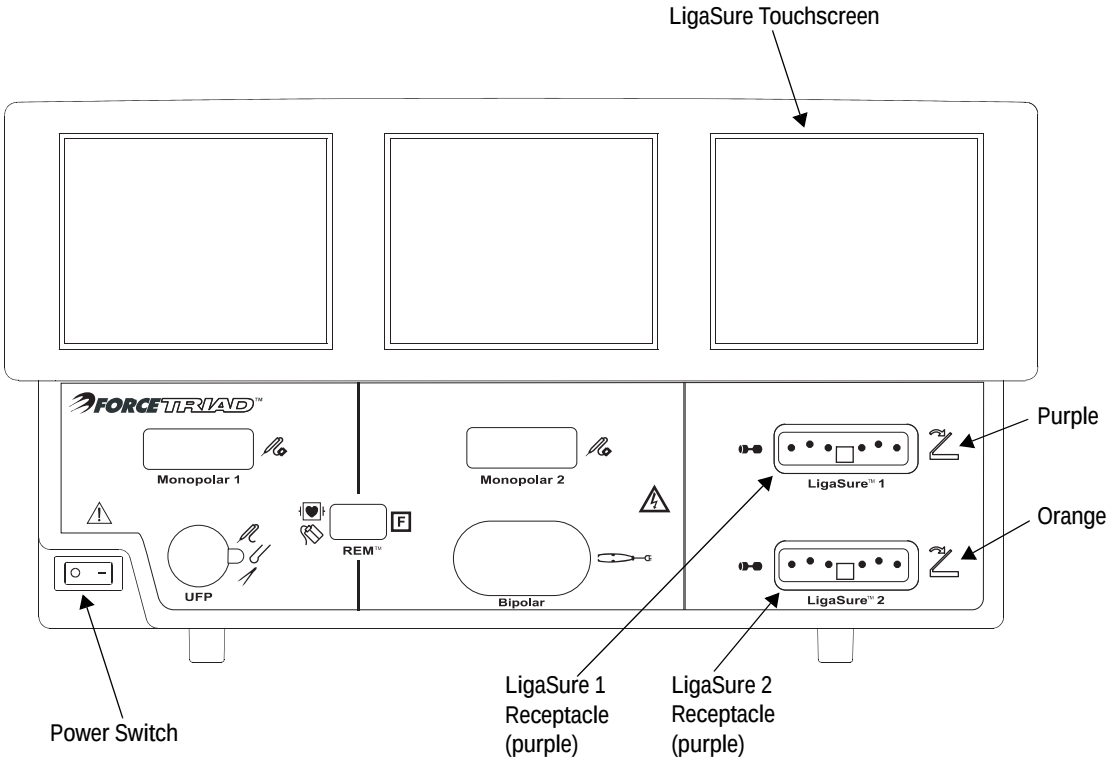
Chapter 6

LigaSure Tissue Fusion

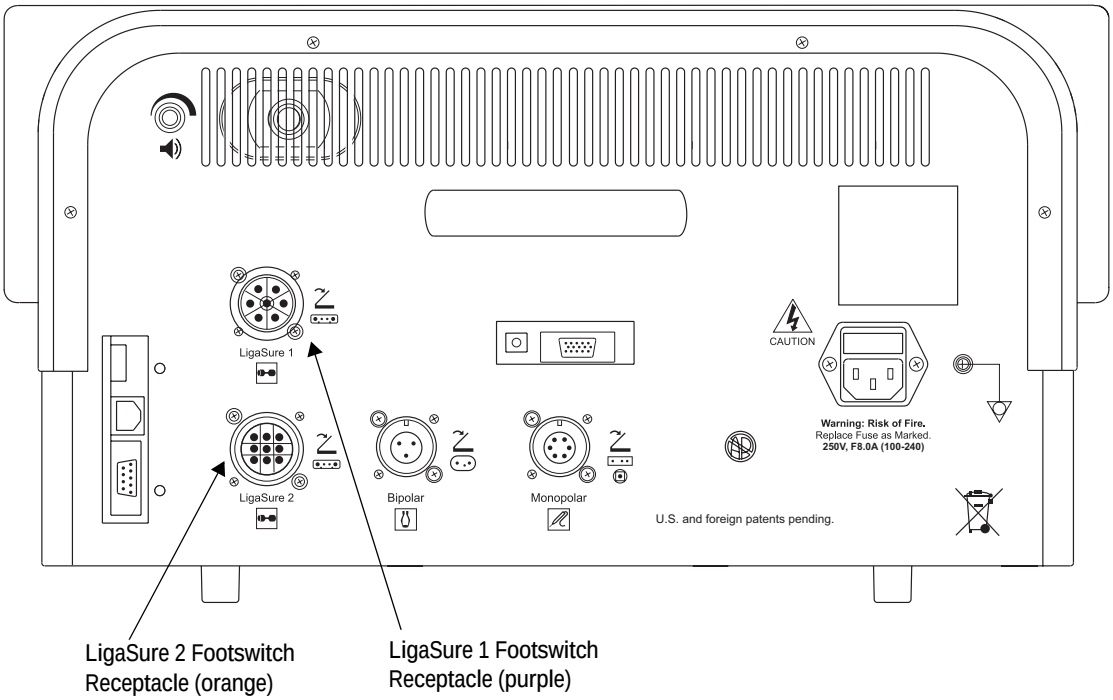
This chapter describes how to set up and operate the LigaSure tissue fusion function of the ForceTriad energy platform.

Caution
Read all warnings, cautions, and instructions provided with this system before use.
Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions for electrosurgical instruments are not included in this manual.

Front Panel LigaSure Features



Rear Panel LigaSure Features



LigaSure Quick Setup Instructions

If you are familiar with the ForceTriad energy platform, you may follow this abbreviated procedure to setup the system for LigaSure tissue fusion.

If you are not familiar with the ForceTriad energy platform, refer to the following sections in this chapter for detailed instructions.

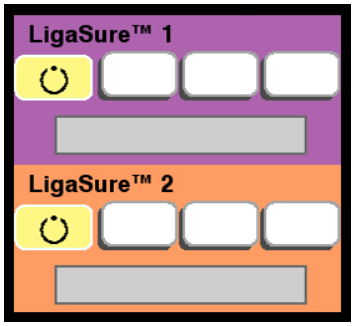
1. Plug the system power cord into the rear panel receptacle.
2. Plug the system power cord into a grounded wall receptacle.

   Note: Do not plug into a power strip or extension cord.
3. Turn on the system and verify that the self-test has successfully completed.
4. If using a footswitch, connect it to the appropriate LigaSure footswitch receptacle on the rear panel.
5. Connect the instrument or instruments to the LigaSure instrument receptacles on the front panel.
6. Verify the bar setting.

LigaSure Function Overview

The LigaSure tissue fusion mode can be used on arteries, veins, and lymphatics up to and including 7 mm in diameter and tissue bundles. This system provides precise energy delivery and electrode pressure to tissues for a controlled time period to achieve a complete and permanent fusion of tissues and vessel lumens. The system has been designed to produce minimal sticking, charring or thermal spread to adjacent tissue.

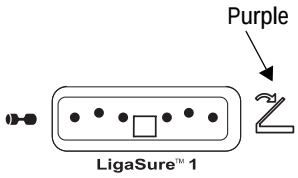
The LigaSure touchscreen is divided into two functional parts: the LigaSure 1 control panel, which controls instruments connected to the LigaSure 1 receptacle; and the LigaSure 2 control panel, which controls instruments connected to the LigaSure 2 receptacle.



Two LigaSure instruments can be set up at one time through this touchscreen, but only one instrument can be activated at one time.

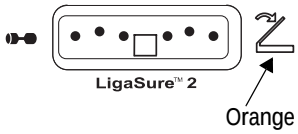
During instrument activation, the status bar in the corresponding LigaSure control panel illuminates blue, and a tone sounds for the duration of energy delivery.

LigaSure 1 Receptacle



The LigaSure 1 receptacle is located directly below the LigaSure touchscreen and is surrounded by a purple color bar with a purple footswitch icon to the right of it. This receptacle accepts all Valleylab LigaSure instruments and can read either the dot patterns or bar codes on the LigaSmart connector. Instruments attached to the LigaSure 1 receptacle are controlled from the upper, purple section of the LigaSure touchscreen.

LigaSure 2 Receptacle



The LigaSure 2 receptacle is located directly below the LigaSure 1 receptacle under the LigaSure touchscreen and is surrounded by a purple color bar with an orange footswitch icon to the right of it. This receptacle accepts all Valleylab LigaSure instruments and can read either the dot patterns or bar codes on the LigaSmart connector. Instruments attached to the LigaSure 2 receptacle are controlled from the lower, orange section of the LigaSure touchscreen.

Warning

Electric Shock Hazard

- Do not connect wet instruments to the energy platform.
- Ensure that all instruments are correctly connected and that no metal is exposed at any connection point.

Connect instruments to the proper receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with LigaSure instruments for proper connection and use.

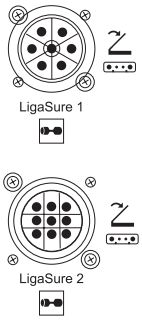
The instrument receptacles on this system are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

Caution

Read the instructions, warnings, and cautions provided with LigaSure instruments before use. Specific instructions are not included in this manual.

Inspect instruments and cords (especially reusable instruments and cords) for breaks, cracks, nicks, and other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

Footswitch



The ForceTriad energy platform in LigaSure mode can accommodate two single-pedal LigaSure footswitches.

If you plan to activate the LigaSure instrument connected to the LigaSure 1 instrument receptacle with a footswitch, attach the purple, seven-pin, LigaSure footswitch connector plug to the purple LigaSure 1 footswitch receptacle on the rear panel.

If you plan to activate the LigaSure instrument connected to the LigaSure 2 instrument receptacle with a footswitch, attach the orange, nine-pin, LigaSure footswitch connector plug to the orange LigaSure 2 footswitch receptacle on the rear panel.

Start System

1. Plug the system power cord into the rear panel receptacle.
2. Plug the system power cord into a grounded wall receptacle.

   Note: Do not plug into a power strip or extension cord.
3. Turn the system power switch to the ON position.

   Note: Verify that the system has successfully completed the start-up self-test. before connecting instruments.

LigaSure Instruments

Reusable Instrument Assembly

Warning

LigaSure instruments that require single use electrodes must be used with the correct electrode type. Use of these instruments with any other electrodes could result in injury to the patient or surgical team, or cause damage to the instrument.

To prepare the reusable LigaSure instruments to be used for the procedure, refer to the following steps for general preparation. To find detailed directions for each instrument, please refer to the individual instrument instructions that accompany each instrument electrode.

1. Slip the base of the disposable electrode's white shaft onto the retaining post on the instrument ring handle.
2. Snap the body of the white electrode shaft onto the instrument handle. The white shaft of the electrode must be completely flush on the reusable instrument shaft.
3. Snap each electrode into the appropriate instrument jaw, matching electrode curvature to jaw curvature. Insert the proximal pin first. Verify that there is no gap between the electrode and the instrument jaw.

   Note: Bent or broken electrode pins will not function properly and may result in an alert situation. In this case, the electrode must be discarded.
4. Gently ratchet the instrument closed on a folded 4x4 to ensure the electrodes are properly seated in the instrument jaws.

Connecting LigaSure Instruments to the Energy Platform

Connect the LigaSmart connector to the LigaSure 1 or LigaSure 2 receptacle on the front panel of the ForceTriad energy platform. The system detects the instrument type and sets the appropriate bar setting in the display. If you have entered settings in the LigaSure touchscreen prior to connecting a LigaSure instrument, these settings will be reset.

Invalid Instrument

If the ForceTriad energy platform does not recognize the attached instrument, the status bar will display the words "Invalid Instrument." Refer to the following steps to resolve the issue.

1. Confirm you are using a LigaSure instrument.
2. Reconnect the instrument using firm pressure to insert the instrument into the LigaSure 1 or LigaSure 2 instrument receptacle.
3. If you still see the words "Invalid Instrument" in the status bar, use a new LigaSure instrument or electrode.

LigaSure Settings

Changing the Energy Delivery Setting

Warning

Confirm proper power or intensity settings before proceeding with surgery.

The green bars on the LigaSure vessel fusion display panel represent different levels of desiccation. Two green bars are the default setting for all LigaSure tissue fusion instruments. This setting allows the energy to precisely affect the target tissue, resulting in permanent tissue fusion with minimal thermal spread to the surrounding tissues. Occasionally the surgeon may encounter tissue or vessels that are fused more effectively with a one or three bar fusion cycle. By selecting one bar, the surgeon can expect a more gentle and typically longer fusion cycle, which can be potentially more effective in thinner tissue bundles and smaller, isolated vessels. By selecting three bars, the surgeon can expect a longer fusion cycle, which can be potentially more effective in thicker tissue bundles.

Notice

The one and three bar seal cycles may result in tissue sticking due to longer dessication periods.

1. You may adjust the instrument setting by touching one of the three setting buttons on the respective LigaSure 1 or LigaSure 2 control panel. The button touched along with the buttons to the left of it become green, and the standby button turns grey.
2. As a safety feature, you may set the ForceTriad energy platform on standby until you are ready for surgery by pressing the standby button.

   When on standby, no energy will be delivered through the LigaSure instrument. If you attempt to activate a LigaSure instrument, a single, short tone will sound.
3. To bring the energy platform out of standby, press a desired bar setting. Previous bar settings will not be stored in standby.

Activating the LigaSure Instrument

1. Activate the LigaSure instrument either by pressing and holding the activation button on the instrument or by stepping on and holding the footswitch pedal. During instrument activation, the status bar in the corresponding LigaSure control panel illuminates blue, and an activation tone sounds for the duration of energy delivery.
2. When the end tone is heard, you may release the activation button or footswitch pedal. In the case of an alert condition, refer to the following section.

Alert Situations

A pulsed tone will sound when an alert condition occurs, and the LigaSure touchscreen will display an alert message that instructs the user on the corrective actions to take. When an alert condition occurs, energy delivery will be interrupted, but will be available immediately after the alert condition has been corrected.

The two alert conditions are:

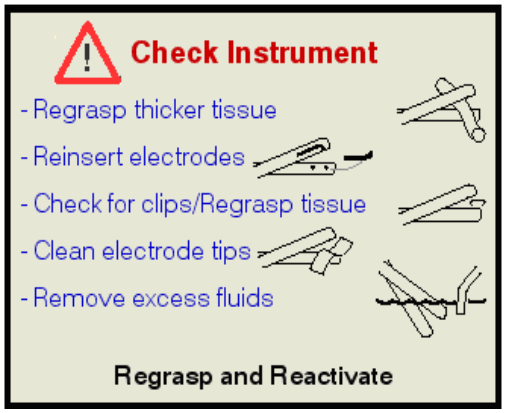
Check Instrument

A ***six-pulsed*** tone will sound when the Check Instrument screen is displayed.

If this message appears, the user should:

1. Release the footswitch pedal or activation button.
2. Open the instrument jaws and inspect for a successful seal.
3. Follow the suggested corrective action on the Check Instrument screen.

If possible, reposition the instrument and regrasp tissue in another location, then reactivate the seal cycle.



Regrasp thicker tissue – Thin tissue; open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure.

Reinsert electrodes – Electrodes may have become dislodged from the instrument.

Check for clips / Regrasp tissue – Avoid grasping objects, such as staples, clips or encapsulated sutures, in the jaws of the instrument.

Clean electrode tips – Use a wet gauze pad to clean surfaces and edges of instrument jaws.

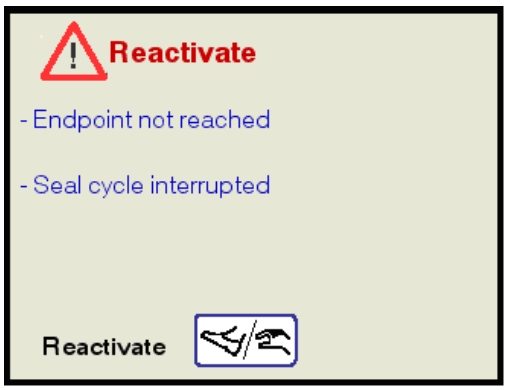
Remove excess fluids – Pooled fluids around the instrument tip; minimize or remove excess fluids.

Reactivate

A ***four-pulsed*** tone will sound when the Reactivate screen is displayed.

If this message appears the user should:

1. Release the footswitch pedal or hand switching button.
2. Reactivate the seal cycle without repositioning the instrument.



Endpoint not reached – Additional time and energy are needed to complete the fusion cycle.

Seal cycle interrupted – The seal cycle was interrupted before completion. The handswitch or footswitch was released before the end tone activated.

Reactivate / Energize – Reactivate the seal cycle without removing or repositioning the instrument.

After Surgery

Disconnect the instruments

1. Turn off the energy platform.
2. Disconnect all instruments from the front panel.
   - If the instrument is single use only (disposable), dispose of it according to the procedures for your institution.
   - If the instrument is reusable, clean and sterilize it according to the manufacturer's instructions for use.
3. Disconnect and store any footswitch(es) used.

Reprocessing Instruments

Clean the Reusable LigaSure Instrument

1. Remove and dispose of single use electrodes.
2. Wipe all surfaces with a cleaning agent and a damp cloth.
3. Follow the procedures approved by your health care facility.
4. Soak in an enzymatic cleaning agent, such as Klenzyme or Enzol, according to the manufacturer's instructions.
5. Scrub all surfaces with a soft brush. It is important that the jaw surfaces and instrument electrode holes are cleaned of blood and tissue to ensure proper electrode assembly.
6. Rinse with water and dry with a soft cloth.

Sterilization Parameters

The hinges on reusable LigaSure instruments are extremely tight and require longer sterilization times to ensure steam penetration into the hinge.

Steam Sterilization - Wrapped

Temperature	Type	Sterilize Time	Dry Time
132 - 138° C (270 - 280° F)	Prevac	10 min	20 min
132 - 138° C (270 - 280° F)	Gravity	15 min	30 min
121 - 131° C (250 - 268° F)	Gravity	30 min	30 min

Steam Sterilization - Unwrapped

Temperature	Type	Sterilize Time	Dry Time
132 - 138° C (270 - 280° F)	Prevac	10 min	1 min
132 - 138° C (270 - 280° F)	Gravity	15 min	1 min

The instructions provided above have been validated by Valleylab as being capable of preparing LigaSure instruments for reuse. It remains the responsibility of the processor to ensure that sterilization is performed using equipment, materials, and personnel that will achieve the desired results. This requires validation and routine monitoring of the process. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Chapter 7

Troubleshooting

Caution
Read all warnings, cautions, and instructions provided with this system before use.
Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions for electrosurgical instruments are not included in this manual.

General Troubleshooting Guidelines

If the ForceTriad energy platform malfunctions, check for obvious conditions that may have caused the problem:

- Check the system for visible signs of physical damage.
- Make sure the fuse drawer is tightly closed.
- Verify that all cords are connected and attached properly.
- If an error code is displayed on the touchscreens, note the code along with all information on the error screen, then turn the system off and turn it back on.

If the malfunction persists, the system may require service. Contact your institution's biomedical engineering department.

REM Alarms

If the ForceTriad energy platform does not sense the correct impedance for the connected REM patient return electrode, monopolar energy will be disabled, the REM symbol will illuminate red and enlarge on both the center and left touchscreen displays, and an alarm tone will sound twice. The REM symbol will return to its smaller size but will remain red, and RF energy will remain disabled until the REM alarm is corrected.

When you correct a REM alarm condition, the system is enabled and the REM alarm indicator illuminates green.

Valleylab recommends the use of Valleylab REM patient return electrodes. Return electrodes from other manufacturers may not provide proper impedance to work correctly with the ForceTriad energy platform.

Correcting a REM Alarm Condition

To correct a REM alarm condition, follow these steps:

1. Inspect the return electrode plug and cord. If you find evidence of cracks, breaks, or other visible damage, replace the return electrode and/or the cord.
2. Verify that the patient return electrode cord is correctly connected to the energy platform.
3. Verify that the return electrode is in good contact with the patient. Follow the instructions for use provided with the Valleylab REM patient return electrode.
4. If the REM alarm persists it may be necessary to use more than one patient return electrode. Refer to the instructions for use with the Valleylab REM patient return electrode for complete information.

Correcting Malfunctions

If a solution is not readily apparent, use the table below to help identify and correct specific malfunctions. After you correct the malfunction, verify that the system completes the self-test as described in the *System Setup* chapter.

Situation	Possible Cause	Solution
Abnormal neuromuscular stimulation *(stop surgery immediately)*	Metal-to-metal sparking	Check all connections to the energy platform, patient return electrode, and active electrodes.
	Can occur during coag	Use a lower power setting for the Fulgurate and the Spray modes.
	Abnormal 50-60 Hz leakage currents	Contact your biomedical engineering department or a Valleylab technical service representative for assistance.
Energy platform does not respond when turned on	Disconnected power cord or faulty wall outlet	Check power cord connections (energy platform and wall outlet). Connect the power cord to a functional outlet.
	Faulty power cord	Replace the power cord.
	Fuse drawer is open or fuses are blown.	Replace the blown fuse(s). Close the fuse drawer. Refer to the ***ForceTriad Energy Platform Service Manual*.**
	Internal component malfunction	Use a backup energy platform. Contact your biomedical engineering department or a Valleylab technical service representative for assistance.
System is on, but did not complete the self-test	Software malfunction	Turn off, then turn on the system.
	Internal component malfunction	Note the code along with all information on the error screen. Note the number and refer to *System Alarms* later in this chapter. Use a backup energy platform. Contact your biomedical engineering department or a Valleylab technical service representative for assistance.

Situation	Possible Cause	Solution
Energy platform is on and instrument is activated, but system does not deliver output	Malfunctioning footswitch or handswitching instrument	Turn off the energy platform. Check and correct all instrument connections. Turn on the energy platform. Replace the instrument if it continues to malfunction.
	Power is set too low	Increase the power setting.
	An alarm condition exists	Note the code along with all information on the error screen. Note the number and refer to *System Alarms* later in this chapter. In case of a REM alarm, refer to *Correcting a REM Alarm Condition* earlier in this chapter.
	Internal component malfunction	Contact your biomedical engineering department or a Valleylab technical service representative for assistance.
	System does not detect tissue fusion instrument	Firmly insert the LigaSmart connector into the appropriate receptacle on the energy platform front panel. Ensure the vessel fusion touchscreen indicates that it has detected the instrument.
	System does not detect monopolar instrument	Firmly insert the Smart connector into the appropriate receptacle on the energy platform front panel. Ensure the monopolar touchscreen indicates that it has detected the instrument.
	System does not detect bipolar instrument	Firmly insert the connector into the appropriate receptacle on the energy platform front panel. Ensure the bipolar touchscreen indicates that it has detected the instrument.

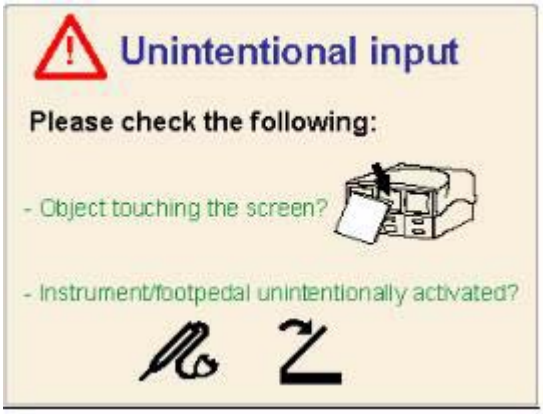
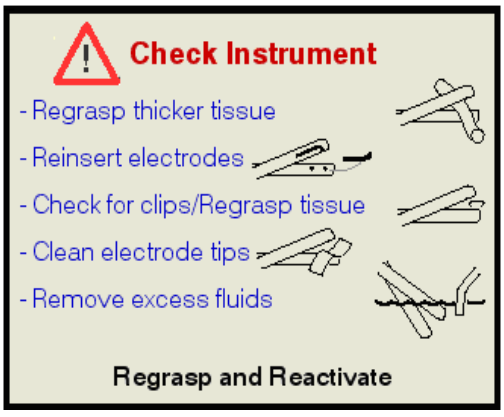
Situation	Possible Cause	Solution
CHECK INSTRUMENT screen appears, a six-pulsed tone sounds, and RF output is disabled	Excessive tissue/eschar on electrode tips or jaws	Clean electrode tips and jaws with a wet gauze pad.
	Electrodes have come loose from the instrument jaws Electrode pins may have been compromised or bent during assembly to the instrument and may need to be replaced	Re-insert the electrode into the instrument jaws making sure that all the electrode pins are firmly seated.
	Metal or other foreign object is grasped within jaws	Avoid grasping objects, such as staples, clips, or encapsulated sutures in the jaws of the instrument.
	Tissue grasped within jaws is too thin	Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure.
	Pooled fluids around instrument tip	Minimize or remove excess fluids.
REACTIVATE screen appears, a four-pulsed tone sounds, and RF output is disabled	The seal cycle was interrupted before completion. The handswitch or footswitch was released before the end tone activated. Additional time and energy are needed to complete the fusion cycle	Reactivate the seal cycle without removing or repositioning the instrument.
Continuous monitor interference	Malfunctioning monitor	Replace the monitor.
	Faulty chassis-to-ground connections	Check and correct the chassis ground connections for the monitor and for the energy platform. Check other electrical equipment in the room for defective grounds.
	Electrical equipment is grounded to different objects rather than a common ground. The energy platform may respond to the resulting voltage differences between grounded objects.	Plug all electrical equipment into line power at the same location. Contact your biomedical engineering department or a Valleylab technical service representative for assistance.

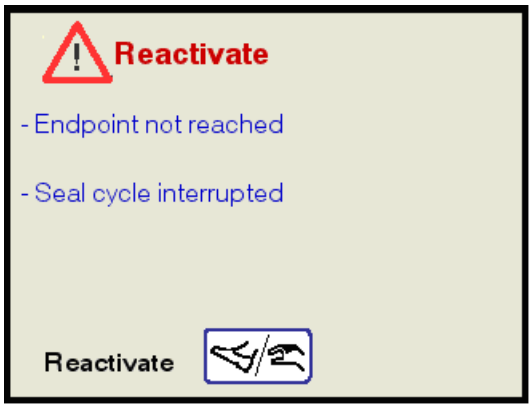
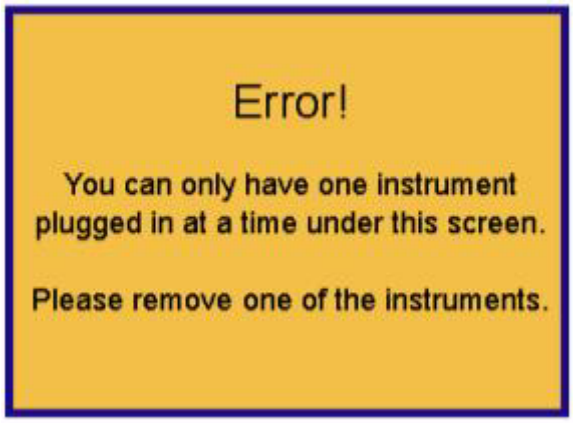
Situation	Possible Cause	Solution
Interference with other devices only when the energy platform is activated	Metal-to-metal sparking	Check all connections to the energy platform, patient return electrode, and instruments.
	High settings used for fulguration	Use lower power settings for fulguration.
	Electrically inconsistent ground wires in the operating room	Verify that all ground wires are as short as possible and go to the same grounded metal.
	If interference continues when the energy platform is activated, the monitor is responding to radiated frequencies.	Ask your biomedical engineering department to check with the manufacturer of the monitor. Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference when the energy platform is activated and minimize the potential for an electrosurgical burn at the site of the monitor electrode.
Pacemaker interference	Intermittent connections or metal-to-metal sparking	Check the active and patient return electrode cord connections. It may be necessary to reprogram the pacemaker.
	Current traveling from active to return electrode during monopolar electrosurgery is passing too close to pacemaker	Consult the pacemaker manufacturer or hospital cardiology department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers. Use bipolar instruments, if possible. If you must use a monopolar instrument, place the patient return electrode as close as possible to the surgical site. Make sure the current path from the surgical site to the patient return electrode does not pass through the vicinity of the heart or the site where the pacemaker is implanted. Always monitor patients with pacemakers during surgery and keep a defibrillator available.
Internal Cardiac Defibrillator (ICD) activation	ICD is activated by energy platform	Stop the procedure and contact the ICD manufacturer for instructions.

System Alarms

Most system alarms require some action on your part to correct the condition; however, some are corrected automatically. Use the following list to determine how to correct an alarm condition.

After correcting the alarm condition, verify that the system completes the self-test as described in the *System Setup* chapter.

Description or Screen	Solution
	Check for stuck instrument buttons and footswitches. Check that nothing is bumping against the touchscreens.
REM Alarm 	Refer to the *REM Alarms* in this chapter.
LigaSure Check Instrument Alert 	Refer to *Alert Situations* in Chapter 6.

Description or Screen	Solution
LigaSure Endpoint Not Reached Alert 	Refer to *Alert Situations* in Chapter 6.
Dual Instrument Alert 	Disconnect one instrument connected under associated screen.
Invalid Instrument Alert 	Disconnect invalid instrument. Use appropriate instrument. Refer to instrument instructions for use for compatibility instructions.

Chapter 8

Maintenance and Repair

This chapter presents the following information:

- The manufacturer’s responsibility
- Routine maintenance
- Returning the energy platform for service
- Service centers

Caution

Read all warnings, cautions, and instructions provided with this system before use.

Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions for electrosurgical instruments are not included in this manual.

Responsibility of the Manufacturer

Valleylab is responsible for the safety, reliability, and performance of the energy platform only if all of the following conditions have been met:

- Installation and setup procedures in this manual are followed.
- Assembly, operation, readjustments, modifications, or repairs are carried out by persons authorized by Valleylab.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as IEC and BSI.
- The equipment is used in accordance with the Valleylab instructions for use.

For warranty information, refer to *Preface* chapter in this manual.

Routine Maintenance

Notice

Refer to the energy platform service manual for maintenance recommendations and function and output power verification procedures.

When should the energy platform be checked or serviced?

Valleylab recommends that the energy platform be inspected by qualified service personnel at least twice a year. This inspection should include adjusting the system to factory specifications.

When should the power cord be checked or replaced?

Check the power cord each time you use the energy platform or at the intervals recommended by your institution. Replace the power cord if you find exposed wires, cracks, frayed edges, or a damaged connector.

When should the fuses be replaced?

An internal component malfunction can damage the fuses. You may need to replace the fuses if the system fails the self-test or if the energy platform stops functioning, even though it is receiving power from a wall outlet. Refer to the service manual for instructions.

Cleaning

Warning

Electric Shock Hazard Always turn off and unplug the energy platform before cleaning.

Notice

Do not clean the energy platform with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the energy platform.

1. Turn off the system and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the energy platform and power cord with a damp cloth and mild cleaning solution or disinfectant. The energy platform will withstand the effects of cleaning over time without degrading the enclosure or display quality.

Product Service

Valleylab recommends that authorized Valleylab personnel service the ForceTriad energy platform, however some service operations can be performed by qualified biomeds.

Returning the Energy Platform for Service

Before you return the energy platform, call your Valleylab sales representative for assistance. If you are instructed to send the energy platform to Valleylab, do the following:

1. Obtain a return authorization number.

   Call the Valleylab Customer Service Center for your area to obtain a Return Authorization Number. Have the following information ready when you call:

   - Hospital/clinic name/customer number
   - Your telephone number
   - Department/address, city, state, and zip code
   - Model number
   - Serial number
   - Description of the problem
   - Type of repair to be done

2. Clean the energy platform.
   See the *Cleaning* section above.

3. Ship the energy platform.
   a. Attach a tag to the energy platform that includes the return authorization number and the information (hospital, phone number, etc.) listed in step 1.
   b. Be sure the energy platform is completely dry before you pack it for shipment. Package it in its original shipping container, if available.
   c. Ship the energy platform, prepaid, to the Valleylab Service Center.

Adjustment to Factory Specification (Calibration)

Valleylab recommends that only Valleylab-authorized personnel calibrate the ForceTriad energy platform. The energy platform incorporates automatic calibration where possible to reduce the required equipment and manual steps.

Software Upgrades

Software upgrades must be performed by authorized personnel only.

Service Centers

For a complete list of service centers worldwide, please refer to the Valleylab website:

http://www.valleylab.com/valleylab/international/service-world.html

Chapter 9

Technical Specifications

All specifications are nominal and subject to change without notice. A specification referred to as “Typical” is within ± 20% of a stated value at room temperature (25° C / 77° F) and a nominal line input voltage.

Caution
Read all warnings, cautions, and instructions provided with this system before use.
Read the instructions, warnings, and cautions provided with electrosurgical instruments before use. Specific instructions for electrosurgical instruments are not included in this manual.

Performance Characteristics

General

Output configuration	Isolated output
Cooling	Natural convection and fan
Display	Three LCD touchscreens
Connector ports	LED illuminated Smart connector readers
Mounting	• ForceTriad energy platform cart (FT900), Universal Mounting cart (UC8009), and/or the UC8010 Overshelf • Operating room boom systems • Any stable, flat surface such as a table or cart top

Dimensions and Weight

Width	45.8 cm (18 in.)
Depth	50.8 cm (20 in.)
Height	25.5 cm (10 in.)
Weight	13.6 kg (30 lbs)

Operating Parameters

Ambient temperature range	+10° C to +40° C
Relative humidity	30% to 75% non-condensing
Atmospheric pressure	700 millibars to 1060 millibars
Warm-up time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the energy platform to reach room temperature before use.

Transport and Storage

Ambient temperature range	-30° C to +65° C
Relative humidity	0% to 90% (non-condensing)
Atmospheric pressure	500 millibars to 1060 millibars
Duration of storage	The ForceTriad energy platform may be stored indefinitely. If the energy platform is stored for over one year, the memory battery must be replaced.

Internal Memory

Nonvolatile, battery-backed RAM	Battery type: Lithium Battery life: 120 mAh
Storage capacity	256 KB

Activation Tone

The audio levels stated below are for activation tones (cut, Valleylab, coag, bipolar, and LigaSure modes) and alarm tones (REM and system alarms) at a distance of one meter.

Volume (adjustable)	45 to 65 dBA
Frequency	Cut: 660 Hz Valleylab: 800 Hz Coag: 940 Hz Bipolar: 940 Hz LigaSure: 440 Hz
Duration	Continuous while the system is activated

Alarm Tone

Volume (not adjustable)	>65 dBA
Frequency	REM: 660 Hz Regrasp: Two tones: High = 985 Hz, Low = 780 Hz Seal Complete: 985 Hz Error/System Alert: Beep tone = 1400 Hz
Duration	REM: Two 1/ 2 second tones separated by 1/2 second for each REM event Reactivate/Regrasp: Four 175 msec tones -- high, low, high -- low separated by 1/2 second Check Instrument: Six 175 msec tones -- high, low, high, low, high, low Seal Complete: Two 175 msec tones separated by 175 msec for each Seal Complete event Error/System Alert: Two 1/ 2 second tones separated by 1/2 second for each Error/System Alert event

REM Contact Quality Monitor

Interrogation frequency	80 kHz ± 10 kHz
Interrogation current	< 100 µA
Interrogation voltage	< 12V RMS

Acceptable Resistance Range

REM resistance measurements are ± 10% during RF activation and ± 5% when RF output is not activated.

REM patient return electrode: 5 to 135 ohms or up to a 40% increase in the initial measured contact resistance (whichever is less).

If the measured resistance is outside the acceptable range(s) noted above, a REM fault condition occurs.

REM Alarm Activation

REM patient return electrode: When the measured resistance exceeds the standard range of safe resistance (below 5 ohms or above 135 ohms) or when the initial measured contact resistance increases by 40% (whichever is less), the REM alarm indicator enlarges and flashes red and yellow, a tone sounds twice, and RF output is disabled. The indicator remains illuminated red and yellow until you correct the condition causing the alarm. Then, the indicator illuminates green and RF output is enabled.

Autobipolar

The ForceTriad energy platform is equipped with an autobipolar feature that allows for automatic activation of bipolar energy.

Note: The autobipolar electrode function requires the use of the Valleylab E0018 bipolar instrument cord.

The autobipolar specifications are:

Interrogation frequency	80 kHz ± 10 kHz
Interrogation current	< 100 µA
Interrogation voltage	< 12V RMS
Activation impedance	20 Ω to 500 Ω

Deactivation impedance	User selectable: 1,500 Ω, 1,800 Ω, 2,000 Ω or 2,200 Ω
Measurement accuracy	± 14% of Full Scale activation impedance while keying active above 10 watts + 50%, -14% of full scale activation impedance while keying active at 10 watts or below ± 5% of Full Scale activation impedance while keying inactive
Keying delay	User selectable in 500 msec increments from 0 sec to 2.5 sec

Duty Cycle

Under maximum power settings and rated load conditions, the ForceTriad energy platform is capable of operating a duty cycle of 25%, defined as 10 seconds active and 30 seconds inactive, in any mode for a period of 4 hours.

Caution

Use of duty cycles greater than 25% (10 seconds active followed by 30 seconds inactive) will increase the risk that heat build-up under a return electrode may be high enough to injure the patient. Do not continuously activate for longer than one minute.

Low Frequency (50/60 Hz) Leakage Current

Enclosure source current, ground open	< 300 µA
Source current, patient leads, all outputs	Normal polarity, intact ground: < 10 µA Normal polarity, ground open: < 50 µA Reverse polarity, ground open: <50 µA Mains voltage on applied part: < 50 µA
Sink current at high line, all inputs	< 50 µA

High Frequency (RF) Leakage Current

	Measured with leads recommended by Valleylab	Measured directly at the energy platform terminals
Bipolar RF leakage current	< 59.2 mA $_{rms}$	< 59.2 mA $_{rms}$
Monopolar RF leakage current	< 150 mA $_{rms}$	< 100 mA $_{rms}$
LigaSure leakage	<132 mA $_{rms}$	< 100 mA $_{rms}$

Input Power

100–120 Volt	220–240 Volt
Maximum VA at nominal line voltage: Idle: 52 VA Bipolar: 450 VA Cut: 924 VA Coag: 530 VA	Maximum VA at nominal line voltage: Idle: 52 VA Bipolar: 450 VA Cut: 924 VA Coag: 530 VA
Input mains voltage, full regulation range: 90–132 Vac	Input mains voltage, full regulation range: 208–264 Vac
Input mains voltage, operating range: 85–132 Vac	Input mains voltage, operating range: 170–264 Vac
Mains current (maximum): Idle: 0.4 A Bipolar: 2.0 A Cut: 7.0 A Coag: 4.0 A LigaSure: 5.0 A	Mains current (maximum): Idle: 0.2 A Bipolar: 1.0 A Cut: 3.5 A Coag: 2.0 A LigaSure: 2.5 A
Mains line frequency range (nominal): 50 Hz to 60 Hz	Mains line frequency range (nominal): 50 Hz to 60 Hz
Fuses (2): 5 mm x 20 mm 8A, 250 V fast blow	Fuses (2): 5 mm x 20 mm 8A, 250 V fast blow
Power cord: 3-prong hospital grade connector	Power cord: 3-prong locally approved connector

Power Cord Specification

This unit was equipped from the factory with a 110 VAC hospital grade NEMA 5-15 power cord. Should the AC power cord need to be replaced to match another plug configuration, the replacement plug/cable/receptacle configuration must meet or exceed the following specifications:

100-120 VAC

Cable - SJT16/3, IEC color code, maximum length 15 ft (5 m)
Plug - minimum 10 A - 125 VAC
Unit receptacle - IEC female, minimum 10 A - 125 VAC

220-240 VAC

Cable - H05VVF3G1.0 VDE, maximum length 15 ft (5 m)
Plug - minimum 6 A - 250 VAC
Unit receptacle - IEC female, minimum 6 A - 250 VAC

Input Frequency

The ForceTriad energy platform operates within specification at all line input frequencies between 48 Hz and 62 Hz. The User does not need to reconfigure the ForceTriad energy platform for different line frequencies.

Input Current

The ForceTriad energy platform draws no more than 10A at any line input voltage.

Backup Power

The ForceTriad energy platform retains all user programmed features, calibration, and statistical data when switched off and unplugged. The ForceTriad energy platform operates within specification when switched over to a supplied line power by hospital backup systems.

Equipotential Ground Connection

An equipotential ground connection is provided to allow connection of the ForceTriad energy platform to ground.

ECG Blanking

An ECG blanking port is provided to signal other devices that the ForceTriad energy platform is active. The receptacle is a 2.5 mm mono jack. It is electrically isolated from the internal ground referenced electronics with the shell electrically connected to the chassis for ESD protection.

Standards and IEC Classifications

The ForceTriad energy platform meets all pertinent clauses of the IEC 60601-1 second edition and IEC 60601-2-2 third edition.

ATTENTION
Consult accompanying documents

The generator output is floating (isolated) with respect to ground.

DANGER
Explosion risk if used with flammable anesthetics

To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified service personnel.

Unit produces non-ionizing radiation

Classified with respect to electrical shock, fire, and mechanical hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1

Symbols

Monopolar instrument receptacle

Monopolar footswitching receptacle

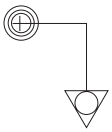
Bipolar instrument receptacle

LigaSure related receptacle or footswitch

Color-coded LigaSure footswitch symbol for matching rear panel connector to front panel receptacle

REM patient return electrode receptacle

Volume adjustment for activation tones



Equipotential grounding point

Equipment should not be disposed in trash

Class I Equipment (IEC 60601-1)

Accessible conductive parts cannot become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor.

Type CF Equipment (IEC 60601-1)/Defibrillator Proof

This generator provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type CF isolated (floating) output and may be used for procedures involving the heart.

This generator complies with the ANSI/AAMI HF18 specifications for “defibrillator proof” designation and IEC 60601-2-2.

Liquid Spillage (IEC 60601-2-2 Clause 44.3)

The ForceTriad energy platform is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which when wetted are likely to adversely affect the safety of the equipment.

Voltage Transients (Emergency Energy Platform Mains Transfer)

The ForceTriad energy platform continues to operate normally with no errors or system failures when transfer is made between line AC and an emergency energy platform voltage source. (IEC 60601-2-2 sub-clause 51.101 and AAMI HF18 sub-clause 4.2.2)

Electromagnetic Compatibility (IEC 60601-1-2 and IEC 60601-2-2)

The ForceTriad energy platform complies with the appropriate IEC 60601-1-2 and 60601-2-2 specifications regarding electromagnetic compatibility.

Notice

The ForceTriad energy platform requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ForceTriad energy platform service manual.

Portable and mobile RF communications equipment can affect the ForceTriad energy platform. Refer to the EMC information provided in the ForceTriad energy platform service manual.

The ForceTriad energy platform meets the following requirements:

ESD Immunity (IEC 60601-1-2 Sub-Clause 36.202 and IEC 61000-4-2)

Radiated Immunity (IEC 60601-1-2 sub-clause 36.202.2 and IEC 61000-4-3)

Electrical Fast Transient/Burst (IEC 60601-1-2 sub-clause 36.202.3.1 and IEC 61000-4-4)

Surge Immunity (IEC 60601-1-2 sub-clause 36.202.3.2 and IEC 61000-4-5)

Emissions (IEC 60601-1-2 sub-clause 36.201.1, IEC 60601-2-2 sub-clause 36 and CISPR 11 Class A)

Harmonic distortion (IEC 60601-1-2 sub-clause 36.201.3.1 and IEC 61000-3-2)

Conducted disturbances (IEC 60601-1-2 sub-clause 36.202.6 and IEC 61000-4-6)

Power frequency magnetic fields (IEC 60601-1-2 sub-clause 36.202.8.1 and IEC 61000-4-8)

Voltage dips, short interruptions and variations (IEC 60601-1-2 sub-clause 36.202.7 and IEC 61000-4-11)

Output Characteristics

Maximum Output for Bipolar, Monopolar, and LigaSure Modes

Power readouts agree with actual power into rated load to within 15% or 5 watts, whichever is greater.

Mode	Open Circuit Peak Voltage (max)	Open Circuit P–P Voltage (max)	Rated Load (max)	Power (max)	Crest Factor*	Duty Cycle
Bipolar						
Low	250 V	500 V	100 Ω	95 W	1.42	N/A
Standard	175 V	350 V	100 Ω	95 W	1.42	N/A
Macro	250 V	500 V	100 Ω	95 W	1.42	N/A
Monopolar Cut						
Cut	920 V	1840 V	300 Ω	300 W	1.42	N/A
Blend	1485 V	2970 V	300 Ω	200 W	2.7	50%
Valleylab (HWD)	2365 V	4730 V	300 Ω	200 W	4.3	25%
Monopolar Coag						
Fulgurate	3050 V	6100 V	500 Ω	120 W	5.55	6.5%
Spray	3625 V	7250 V	500 Ω	120 W	6.6	4.6%
LigaSure	287.5 V	575 V	20 Ω	350 W	1.42	N/A

** An indication of a waveform's ability to coagulate bleeders without a cutting effect.*

Available Power Settings in Watts

Bipolar and Autobipolar (All Modes)

1	2	3	4	5	6	7	8	9	10
11	12	13	14	15	16	17	18	19	20
21	22	23	24	25	26	27	28	29	30
31	32	33	34	35	36	37	38	39	40
45	50	55	60	65	70	75	80	85	90
95									

Monopolar Cut

1	2	3	4	5	6	7	8	9	10
11	12	13	14	15	16	17	18	19	20
21	22	23	24	25	26	27	28	29	30
31	32	33	34	35	36	37	38	39	40
45	50	55	60	65	70	75	80	85	90
95	100	110	120	130	140	150	160	170	180
190	200	210	220	230	240	250	260	270	280
290	300								

Monopolar Blend

1	2	3	4	5	6	7	8	9	10
11	12	13	14	15	16	17	18	19	20
21	22	23	24	25	26	27	28	29	30
31	32	33	34	35	36	37	38	39	40
45	50	55	60	65	70	75	80	85	90
95	100	110	120	130	140	150	160	170	180
190	200								

Valleylab

1	2	3	4	5	6	7	8	9	10
11	12	13	14	15	16	17	18	19	20
21	22	23	24	25	26	27	28	29	30
31	32	33	34	35	36	37	38	39	40
45	50	55	60	65	70	75	80	85	90
95	100	110	120	130	140	150	160	170	180
190	200								

Monopolar Coag

1	2	3	4	5	6	7	8	9	10
11	12	13	14	15	16	17	18	19	20
21	22	23	24	25	26	27	28	29	30
31	32	33	34	35	36	37	38	39	40
45	50	55	60	65	70	75	80	85	90
95	100	110	120						

Output Waveforms

Tissue Sensing Technology, an automatic adjustment, controls all modes. As tissue resistance increases from zero, the energy platform outputs constant current followed by constant power followed by constant voltage. The maximum output voltage is controlled to reduce capacitive coupling and video interference and to minimize sparking.

Bipolar

Low	472 kHz sinusoid continuous
Standard	472 kHz sinusoid continuous
Macro	472 kHz sinusoid continuous

Monopolar Cut

Cut	472 kHz sinusoid continuous
Blend	472 kHz bursts of sinusoid, recurring at 26.21 kHz intervals. 50% duty cycle.

Valleylab

Valleylab	472 kHz bursts of sinusoid, recurring at 28.3 kHz intervals. 25% duty cycle.

Monopolar Coag

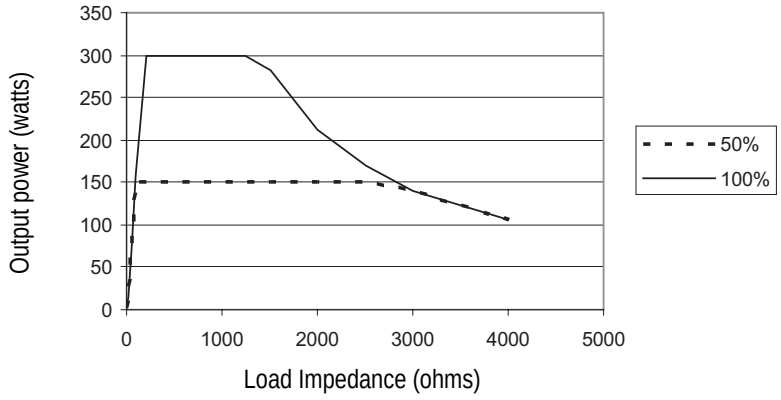
Fulgurate	472 kHz damped sinusoidal bursts with a repetition frequency of 30.66 kHz. 6.5% duty cycle.
Spray	472 kHz damped sinusoidal bursts with a randomized repetition centered at 21.7 kHz. 4.6% duty cycle.

Output Power vs. Resistance Graphs

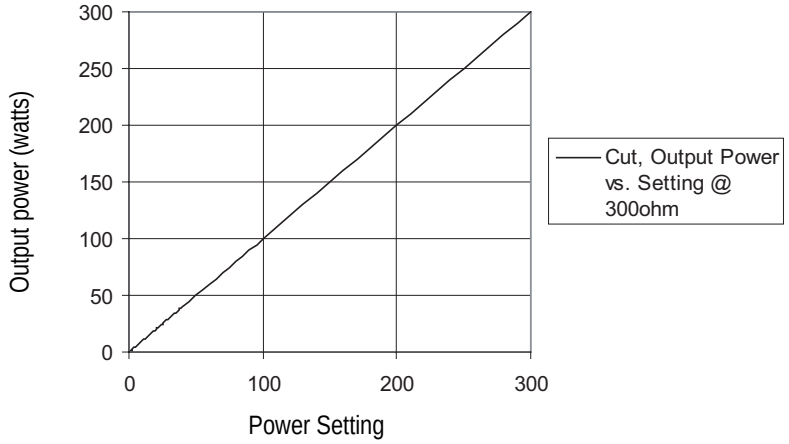
Monopolar Graphs

Pure Cut

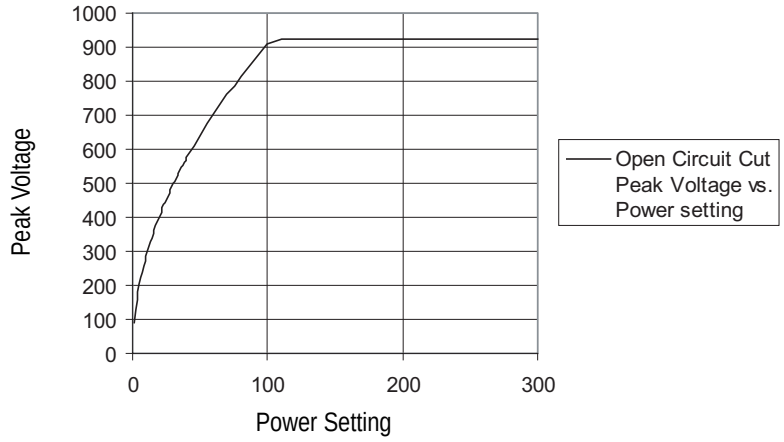
Output power versus impedance for Pure cut power



Output power versus power setting for Pure cut power

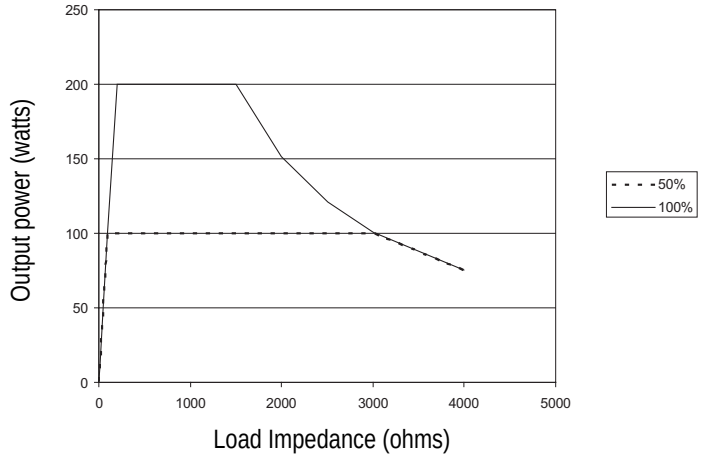


Peak voltage versus power setting for Pure cut power

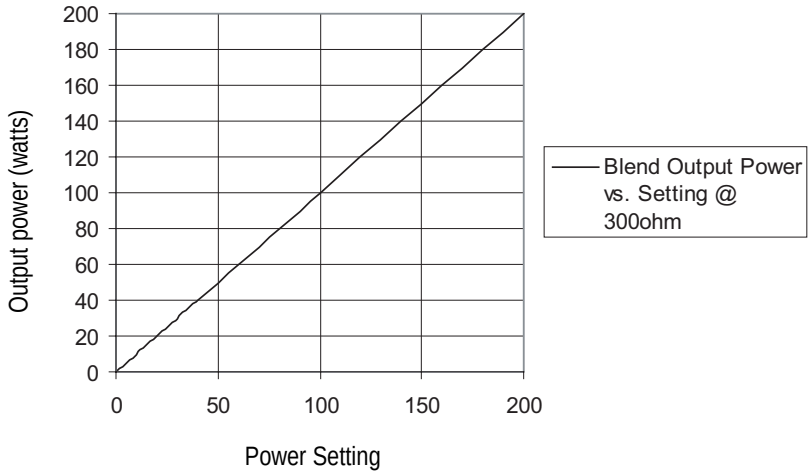


Blend

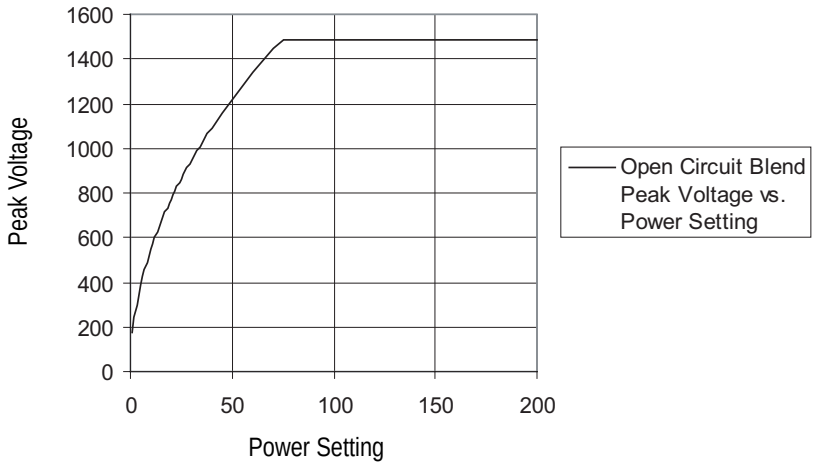
Output power versus impedance for Blend power



Output power versus power setting for Blend power

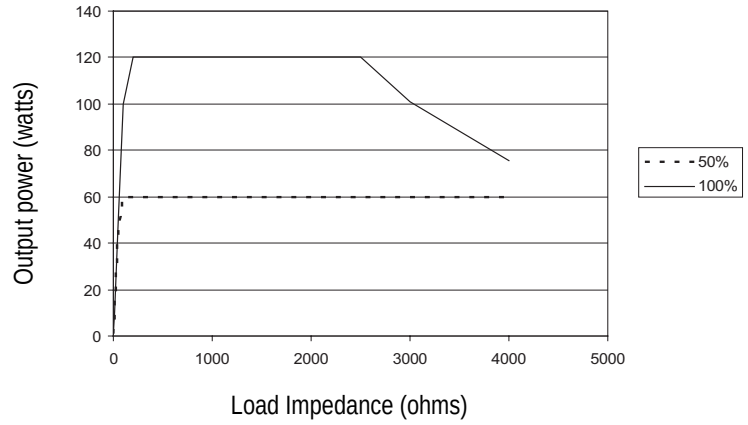


Peak voltage versus power setting for Blend power

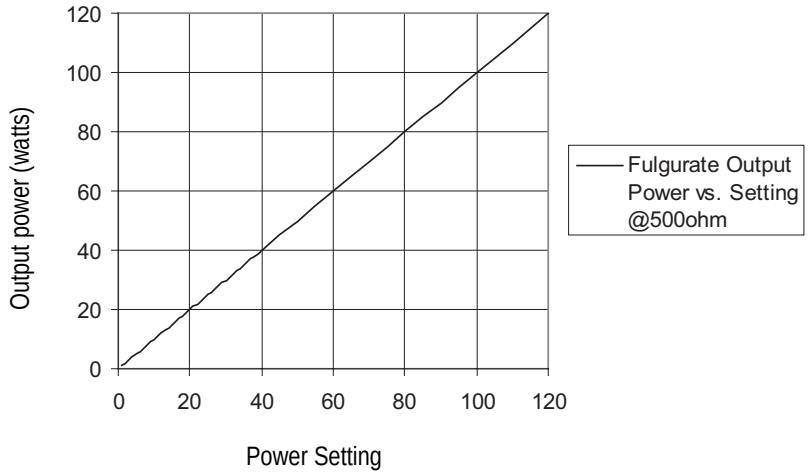


Fulgurate

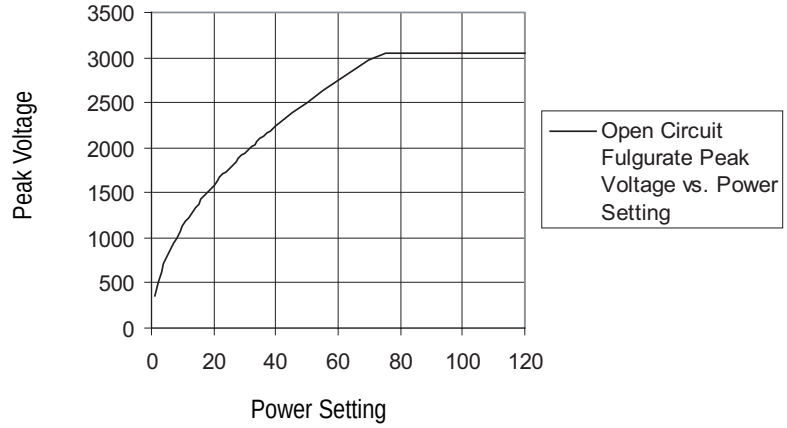
Output power versus impedance for Fulgurate power



Output power versus power setting for Fulgurate power

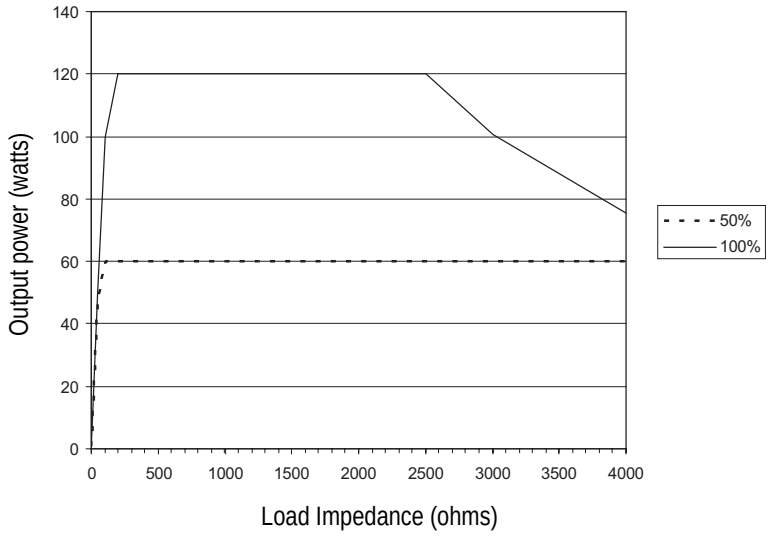


Peak voltage versus power setting for Fulgurate power

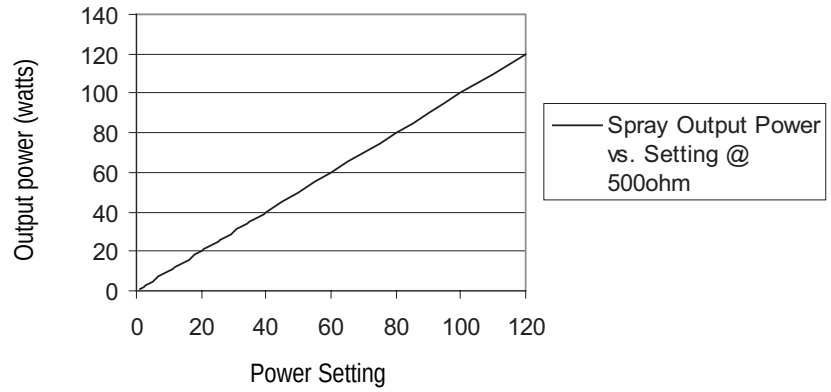


Spray

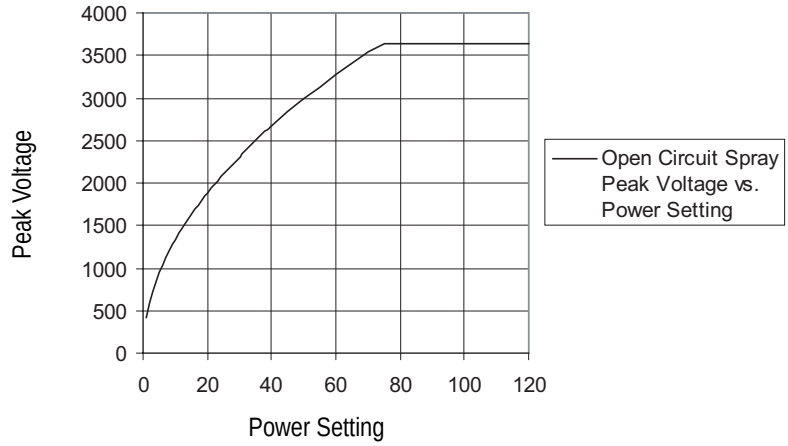
Output power versus impedance for Spray power



Output power versus power setting for Spray power

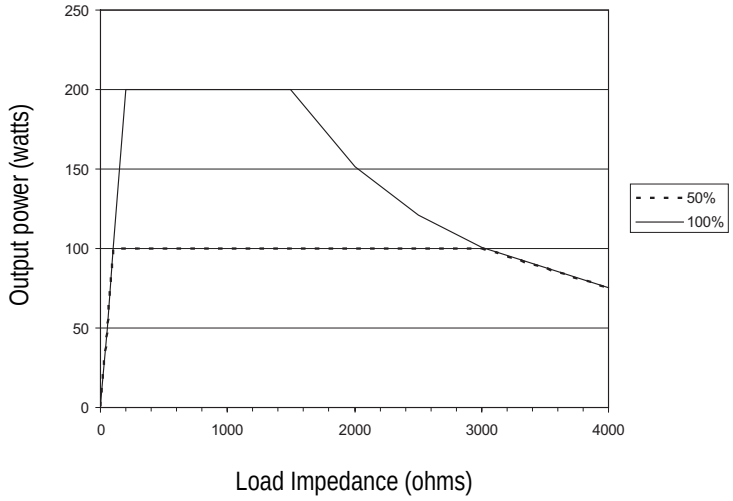


Peak voltage versus power setting for Spray power

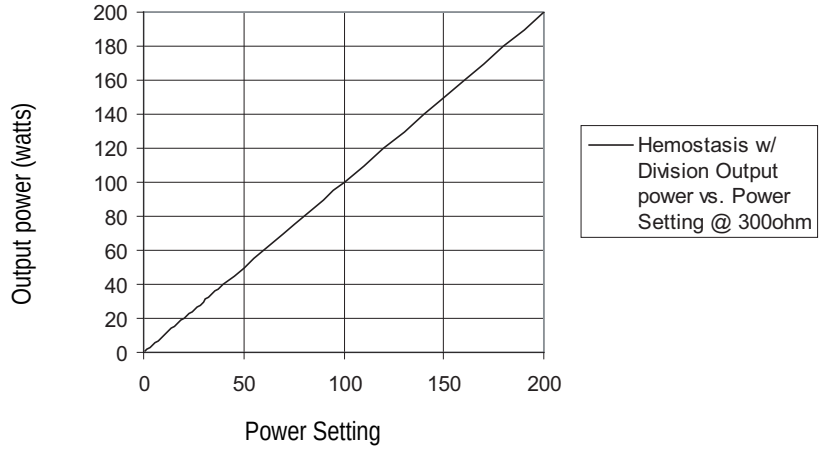


Valleylab

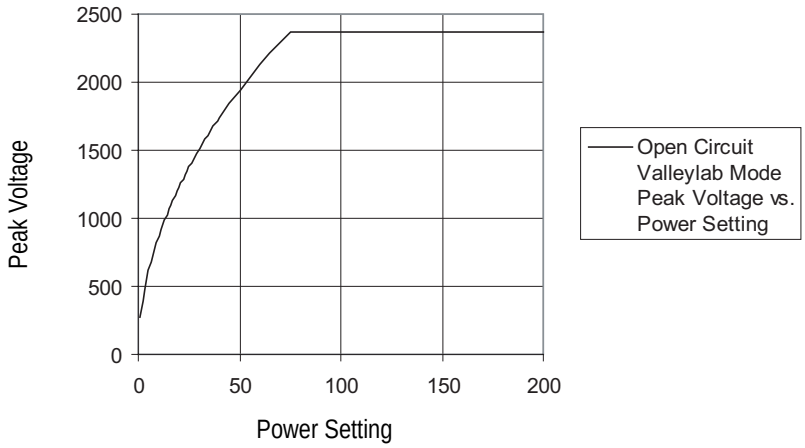
Output power versus impedance for Valleylab power



Output power versus power setting for Valleylab power



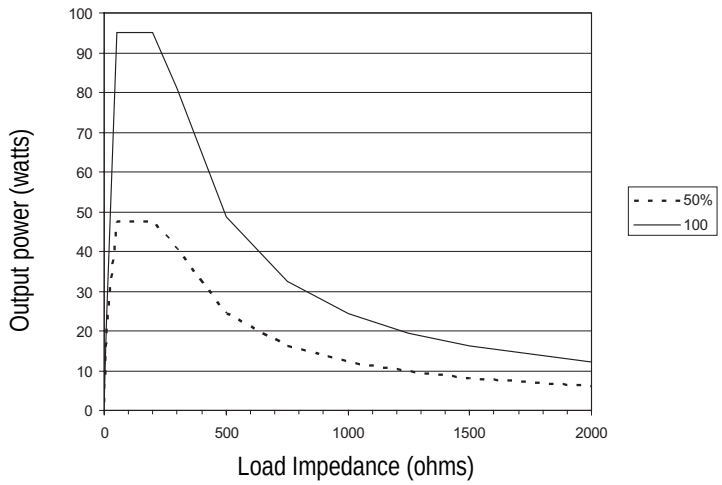
Peak voltage versus power setting for Valleylab power



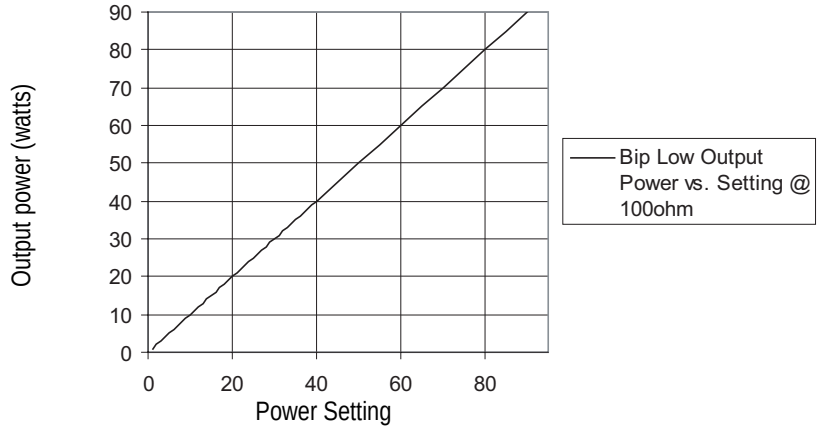
Bipolar Graphs

Bipolar Low

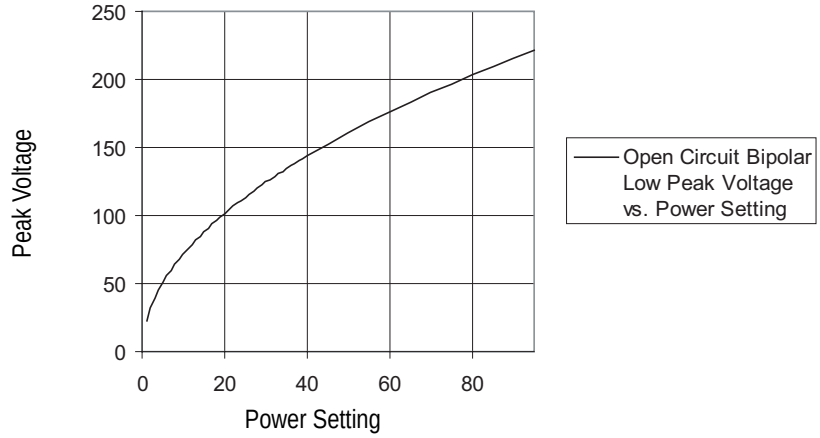
Output power versus impedance for Bipolar Low power



Output power versus power setting for Bipolar Low power

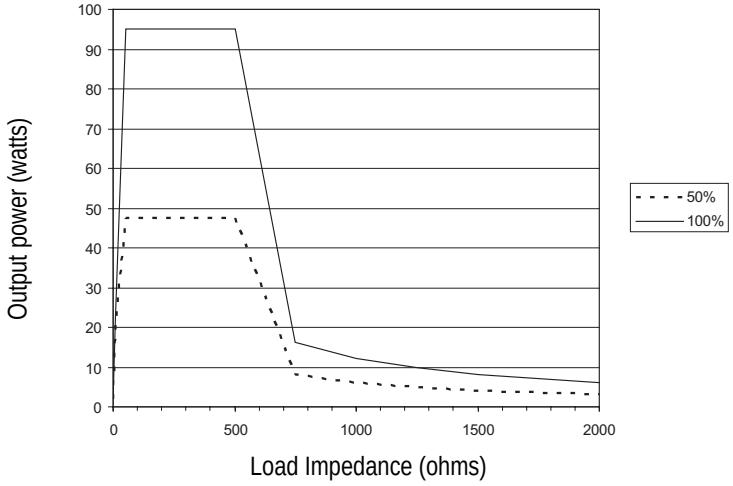


Peak voltage versus power setting for Bipolar Low power

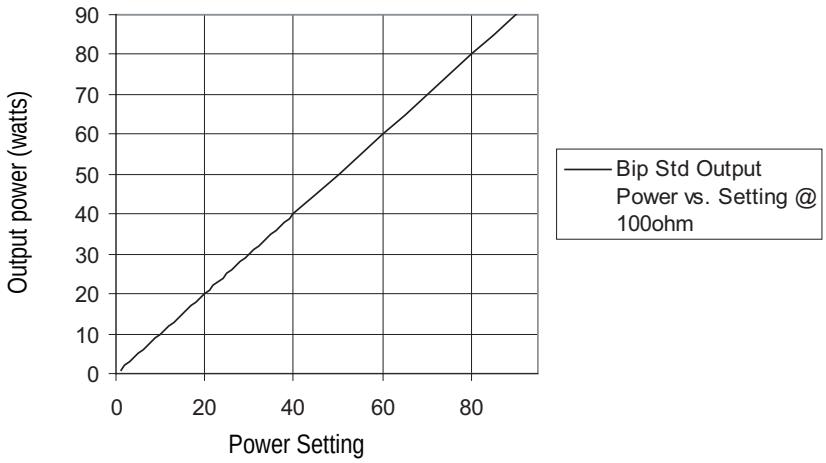


Bipolar Standard

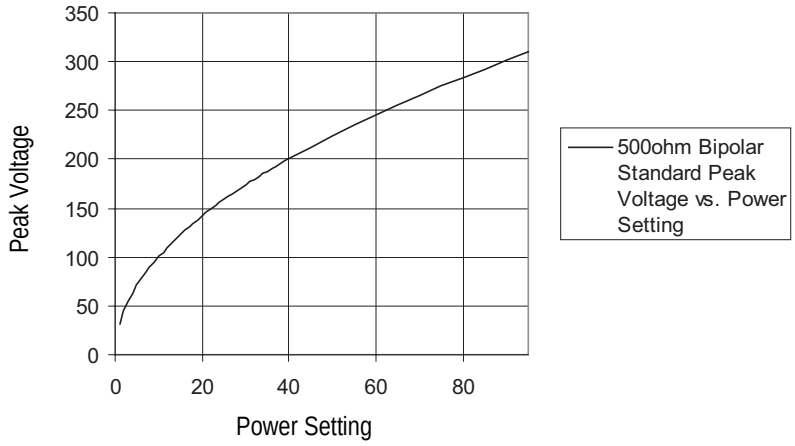
Output power versus impedance for Bipolar Standard power



Output power versus power setting for Bipolar Standard power



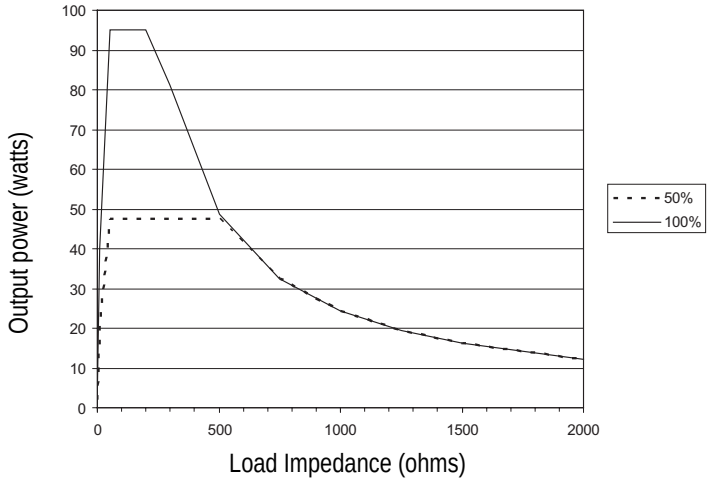
Peak voltage versus power setting for Bipolar Standard power



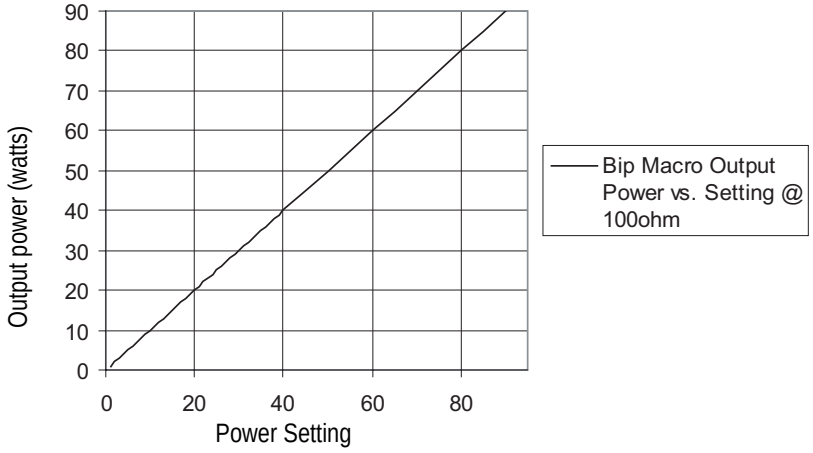
Note: Maximum peak voltage in the Bipolar Standard mode occurs at 500 Ω, not open circuit.

Bipolar Macro

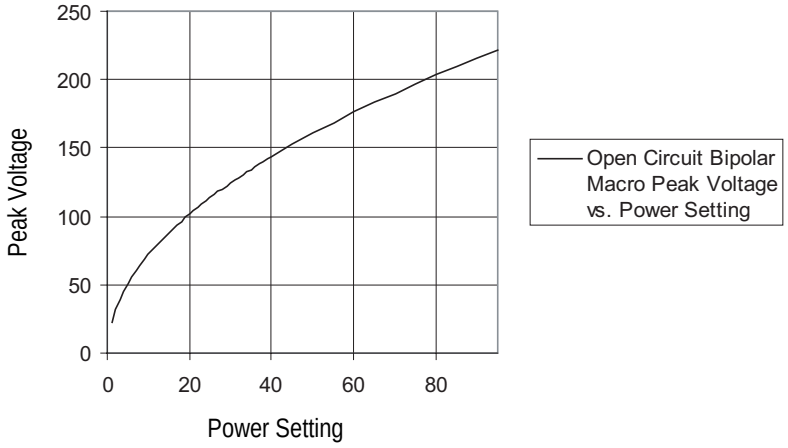
Output power versus impedance for Bipolar Macro power



Output power versus power setting for Bipolar Macro power

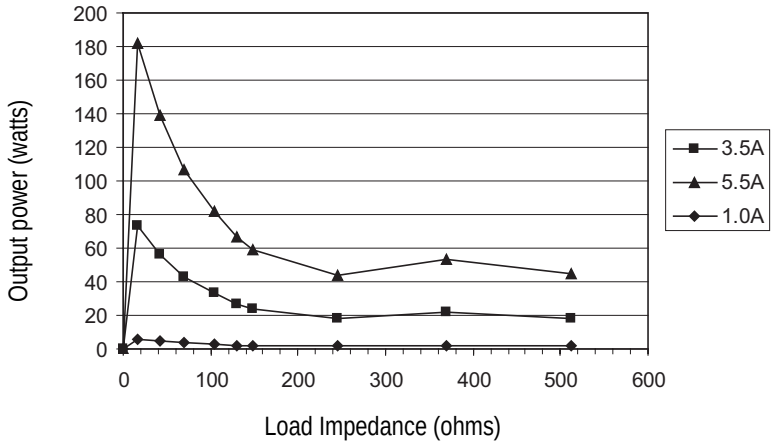


Peak voltage versus power setting for Bipolar Macro power

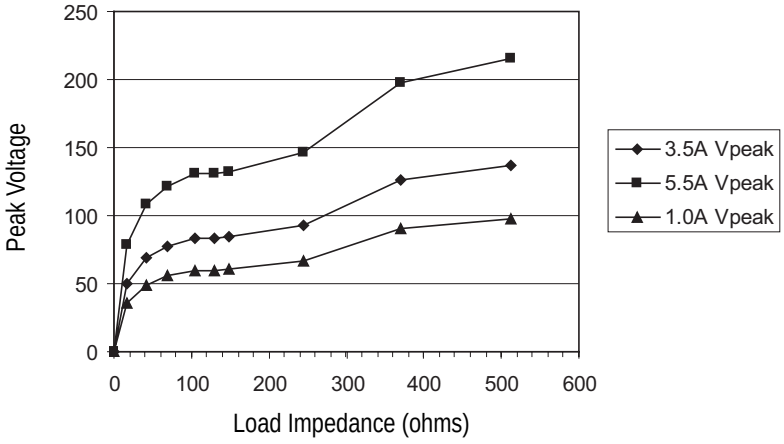


LigaSure

Output power versus impedance for LigaSure power



Peak voltage versus impedance for LigaSure power



Valleylab™